**Of Regulating Healthcare AI and Robots**

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## I. INTRODUCTION

The foundations for the safety regulation of healthcare are twofold: state medical practice acts and the federal laws that require the approval and surveillance of drugs and devices. The former have been with us for well over a century,[1] the latter for eighty years in the case of drugs[2] and almost fifty years for devices.[3] The key concept in the practice acts is the "practice of medicine." In device regulation, it is the functional definition of "device" contained in the Federal Food, Drug, and Cosmetic Act (FD&C Act).[4] Over time, these foundational regulatory precepts have been joined by a patchwork of additional provisions goaled with the regulation of particular entities, such as hospitals[5], or specific activities, such as data protection[6] and research involving human subjects.[7]

This Article argues that advances in healthcare artificial intelligence (AI) will seriously challenge the robustness and appropriateness of our current healthcare regulatory models. Initially and as detailed in Part III, healthcare AI will join other technologies such as big data and mobile health apps in highlighting current deficiencies in healthcare regulatory models, particularly in data protection. In particular, healthcare AI will challenge regulatory models that use binary formulations such as "safe" or "unsafe." As a result, and detailed in Part IV, the regulation of AI will require some fresh thinking: future AI regulation should be underpinned by broadly embraced ethical and moral values, and must be holistic, universal, contextually aware, and responsive to what will be major shifts in the man-machine relationship.

This Article proceeds in four parts and provides a comprehensive examination of current and future healthcare AI regulation. Part II provides context by suggesting a typology for healthcare AI technologies. In large part, the ordering of these types of healthcare AI is based on when their substitutive effects will be felt, identifying from first to last healthcare functions or tasks that will experience

1. *See generally* Clinton Sandvick, *Enforcing Medical Licensing in Illinois: 1877-1890*, 82 YALE J. BIOLOGY MED. 67, 67 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2701151/. For the definition of drug see 21 U.S.C. § 321(g) (2018).

2. The Federal Food, Drug, and Cosmetic (FDC) Act of 1938, Pub. L. No. 75-747, 52 Stat. 1040 (codified as amended in scattered sections of 21 U.S.C.).

3. The Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

4. 21 U.S.C. § 321(h) (2018); *see generally* https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm300639.htm

5. *See, e.g.*, Illinois Hospital Licensing Act, 210 Ill. Comp. Stat. 85/.

6. *See, e.g.*, Centers for Medicare & Medicaid Services, HIPAA Basics for Providers: Privacy, Security, and Breach Notification Rules (Sept. 2018), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/HIPAAPrivacyandSecurityTextOnly.pdf.

7. 45 C.F.R. § 46 (2018).

augmentation or replacement by AI. Part III is a critical examination of the existing healthcare regulatory structure as it would be applied to AI. It sketches out the public and private ordering systems (device regulation, licensure, privacy and confidentiality, reimbursement, market forces, and litigation) that apply today and identifies their weaknesses in regulating healthcare AI. Part IV then suggests the imperatives for a new regulatory structure, one that relies less on the sense that we *know* the "practice of medicine" or "device" when we *see* it. There are some specific challenges here. The foremost is that future regulation *should* be built on top of some generally accepted normative principles. However, many of these normative principles are either in their infancy or lack universality, being illustrative of diverse cultural approaches to the provision of healthcare. Notwithstanding, some broad regulatory imperatives are suggested; from fairly obvious baselines such as quality, safety, and efficacy and a modern data protection construct to more nuanced requirements such as cost-effectiveness, empathy, health equity, and transparency.

By necessity, this article discusses a broad swathe of technologies and their implementation. Some of the discussions involve AI, others AI that employs machine learning (ML) or neural networks, and others robots that are AI and data-driven. The underlying technology is AI, and whether a particular discussion involves healthcare AI, robots, or ML will be a function of how the AI finds physical expression.[8] Therefore, to reduce repeated compound references (e.g., AI and robots) the term AI (or healthcare AI) is used as a comprehensive label for the technologies relying on context or more specific labelling where that is necessary.

The underlying assumptions of this article are that healthcare AI is advancing at a far greater pace than prior healthcare technology implementations and is outpacing any adaptation by extant regulatory models. The arguments moving forward are not merely for more or better regulation. Rather, they begin by suggesting the normative discussions that have to precede those regulatory steps and then sketch out the likely pillars for the future regulation of healthcare AI.

## II. DEFINITION, TYPOLOGY, AND SUBSTITUTION

The interrelationship between data, data analytics, AI, ML, and robotics is complex. Diagnostic, predictive, and prescriptive analytics are often powered by AI; the most recent AI involves ML, with the machine being trained on massive datasets. Current technology underlying AI involves neural networks and special algorithms that are modelled on the human brain, often with the ability to adapt or teach themselves. Some AI finds expression in the physical world through humans.

8. Nicolas Terry, *Appification, AI, and Healthcare's New Iron Triangle*, 20 J. HEALTH CARE LAW & POLICY, 117, 137 (2018).

Other forms find expression through machines that we call robots.

The European Commission's guidance on ethical AI included a useful working definition:

> Artificial intelligence (AI) systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their previous actions.[9]

Of course, definitional labelling can have rhetorical effects. For example, AI is broadly understood to stand for Artificial Intelligence,[10] but in its 2018 policy recommendations the American Medical Association (AMA) preferred the phrase "augmented intelligence."[11] In a supporting document, the AMA noted that, in health care, a more appropriate term is "augmented intelligence" (AI) because it reflects the enhanced capabilities of human clinical decision making when coupled with these computational methods and systems."[12] Of course, that labelling hides a conclusion; that the physician, not the AI, will have primacy. "Artificial intelligence" is also viewed by some as threatening, perhaps explaining why Google now just uses the acronym "AI."[13]

Our current healthcare AI also suffers from sorting errors because of inaccurate labelling. For example, today's surgical "robots" use teleoperation technology that translates human interactions into minimally-invasive micro surgery; as such they are not worthy of an autonomy-suggesting label.[14] Descriptions of healthcare AI can also be under-inclusive, tending to concentrate on large AI projects such as IBM's *Watson Health*, GE Healthcare's *Edison*, or

9. EUROPEAN COMMISSION, ETHICS GUIDELINES FOR TRUSTWORTHY AI 36 (2019) [hereinafter EU GUIDANCE ON AI].

10. Robert L. Adams, *10 Powerful Examples of Artificial Intelligence in Use Today*, FORBES (Jan. 10, 2017), https://www.forbes.com/sites/robertadams/2017/01/10/10-powerful-examples-of-artificial-intelligence-in-use-today.

11. Press Release, AMA, AMA Passes First Policy Recommendations on Augmented Intelligence (June 14, 2018), https://www.ama-assn.org/press-center/press-release/ama-passes-first-policy-recommendations-augmented-intelligence

12. Am. Med. Assoc., Augmented Intelligence in Health Care, 2018 at 2, https://www.ama-assn.org/system/files/2019-01/augmented-intelligence-policy-report.pdf.

13. GOOGLE AI, https://ai.google.

14. *See generally* DA VINCI SURGERY, http://www.davincisurgery.com.

Google's *DeepMind* at the expense of consumer-facing products such as apps and smart watches that increasingly contain AI, even neural networks.

Discussions about AI can also be derailed by physical form. Perhaps not surprisingly given their conjectural role of substituting for humans, robots often are built in humanoid shapes. This tendency has been amplified by many of the literary and film iterations of robots that have adopted human-like form or have even been part man, part robot. Some depictions have been terrifying,[15] others cute with important narrative roles.[16] Others feed into the regulatory discussion, as writers have increasingly explored both dangerous and intimate interactions and interrelationships between man and machine.[17] Humanoid form also increases the likelihood that the AI will have social valence, that humans will view some applications as more than mere objects. As Ryan Calo has argued, "to a greater degree than perhaps any technology in history, robots have a social valence to people."[18]

In cases where healthcare AI is given humanoid form, heightened regulation may be justified because of broad concerns caused by intimacy.[19] Traditionally, our regulatory systems (primarily licensure and liability) have carefully regulated intimate relationships such as those between physician and patient because of concerns such as informational asymmetry and patient vulnerability.

Overall, however, few healthcare robots are likely to be humanoid, rather, their shape(s) will follow their function[20] Kevin Kelly makes a similar point about the cognitive nature of AI or robots: "To demand that artificial intelligence be humanlike is the same flawed logic as demanding that artificial flying be birdlike, with flapping wings. Robots will think different." Thus, it is likely an error to use resemblance (or lack thereof) to familiar persons or objects as classification

15. Such as THE TERMINATOR (Orion Pictures 1984) or MORGAN (20th Century Fox 2016).

16. Such as the droids in the STAR WARS series or Commander Data in Star trek the Next Generation. Brett White, *15 Best Star Wars Droids Ever*, CBR (Nov. 1, 2016), https://www.cbr.com/15-best-star-wars-droids-ever; *Data*, STAR TREK http://www.startrek.com/database_article/data.

17. *See, e.g.*, Megan Eisenfelder, *Westworld: Are the Hosts Human?*, GROUNDS (Jan. 3, 2017), http://www.vabioethics.com/content/2017/1/3/westworld-are-the-hosts-human; *Humans: About the Show*, AMC, http://www.amc.com/shows/humans/exclusives/about. *See also* https://www.cnn.com/2018/12/28/health/rise-of-digisexuals-intl/index.html; https://www.wired.com/2017/10/hiroshi-ishiguro-when-robots-act-just-like-humans.

18. Ryan Calo, *Robotics and the Lessons of Cyberlaw*, 103 Cal. L. Rev. 513, 546 (2015).

19. Alex Mar, *Love in the Time of Robots*, WIRED (Oct. 17, 2017), https://www.wired.com/2017/10/hiroshi-ishiguro-when-robots-act-just-like-humans; Andrea Morris, *Prediction: Sex Robots are the Most Disruptive Technology We Didn't See Coming*, FORBES (Sept. 25, 2018), https://www.forbes.com/sites/andreamorris/2018/09/25/prediction-sex-robots-are-the-most-disruptive-technology-we-didnt-see-coming

20. *See, e.g.*, U.S. Food & Drug Administration, Premarket Approval, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p080009; *see generally* Cade Metz, *Inside Google's Rebooted Robotics Program*, N.Y. TIMES (Mar. 26, 2019), https://www.nytimes.com/2019/03/26/technology/google-robotics-lab.html (discussing Google robotics and noting an increased integration of machine learning and less interest in humanoid form)

touchstones.

The power of machine learning and the neural networks underlying it are frequently demonstrated by AI's growing power to win complex games. While there is nothing particularly new in pursuing that endeavor, the most recent example, the AlphaZero algorithm, is of great importance both because it is essentially self-taught and can defeat computing AI systems programmed to win specific games.[21] This suggests that neural networks are evolving in ways that not only mimic but also exceed the human brain.[22]

An open question is when we will reach (or recognize) the tipping point of healthcare AI implementation. A somewhat skeptical view is justified because healthcare has exhibited a dismal record for adopting cutting edge technologies.[23] After all, by one estimate seventy-five percent of all medical communications still rely on facsimile machines.[24] Expressed differently, "[p]atients haven't always benefited from the promises of technology . . . [and] [t]echnology companies have given patients few reasons to trust them with all their medical data."[25] Notwithstanding, AI has already insinuated itself into many aspects of healthcare delivery, medicine, and research. Examples include everything from custodial tugs, mobile health apps and wearables, and analytics packages designed to reduce readmissions. However, AI's first major impact, that "gotcha moment," will be when its predictive abilities begin to dominate the space. Today, the practice of medicine is dominated by heuristics and rule-based systems. The former, while efficient in that they quickly access already cached data and (apparently) similar decisions, are prone to cognitive biases.[26] While AI has its own bias issues (including the cognitive biases of programmers and skewed data sets used for training), it should comfortably outperform heuristics and with fewer errors.[27] The latter rule-based systems (for example, if-then rules in clinical practice guidelines) are typically derived from comparisons of inputs and outputs; for example, in the event of state A, use treatment Y, but don't use treatment Z in the event of state B. In the first case, any false positives (bad outcomes from using Y) are outnumbered

21. David Silver et al, *A General Reinforcement Learning Algorithm That Masters Chess, Shogi, and Go Through Self-play*, 362 SCIENCE 1140, 1140-44 (2018). *See also* David Silver et al, *Mastering the Game of Go Without Human Knowledge*, 550 NATURE 354, 354-59 (2017).

22. James Kirkpatrick et al., *Overcoming Catastrophic Forgetting in Neural Networks*, 114 PROC. NAT'L ACAD. SCI. 3521, 3521 (2017).

23. Nicolas Terry, *Information Technology's Failure to Disrupt Healthcare*, 13 Nev. L.J. 722 (2013)

24. Sara Kliff, *The Fax of Life*, VOX (Jan 12, 2018), https://www.vox.com/health-care/2017/10/30/16228054/american-medical-system-fax-machines-why.

25. Michael Mittelman, Sarah Markham & Mark Taylor. Patient Commentary: Stop Hyping Artificial Intelligence—Patients Will Always Need Human Doctors, 363 BMJ k4669 (2018).

26. *See generally* The Joint Commission, *Cognitive Biases in Health Care* (Oct. 2016), https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_28_Oct_2016.pdf

27. Jim Guszcza & Nikhil Maddirala, *Minds and Machines*, 19 DELOITTE REV. 7 (2016), https://www2.deloitte.com/insights/us/en/deloitte-review/issue-19/art-of-forecasting-human-in-the-loop-machine-learning.html ("Unaided judgment is an unreliable guide to action")

by the good outcomes. In the second case, there are too many bad outcomes to outnumber any false negatives (persons with Z who could benefit from B). Once these issues are understood as prediction problems, properly trained AI can be used to make far better determinations about populations that will benefit from Y and Z decisions that are not frozen by rules and, as more decisions are made, continually improve.[28]

In an attempt to construct a timeline for, or manage apprehension about, AI, a great deal of reliance has been placed on substitution: a metric that attempts to predict the likelihood of a particular human endeavor or economic activity being supplemented or replaced by AI. By that measure, healthcare professionals have relatively low potential for substitution.[29] Indeed, a White House AI study reported that while "AI technology . . . may improve early detection of some cancers or other illnesses," it will nevertheless take a human "to work with patients to understand and translate patients' symptoms, inform patients of treatment options, and guide patients through treatment plans."[30] As emphasized below the value of the substitution metric must not be overstated. Further, some healthcare AI implementations may jump ahead, resorting the substitution list such that, for example, an apparently "safe" medical subspecialty is replaced by AI.

### *A. Typology*

Although the substitution metric must be used cautiously, the likelihood of substitution provides one method of typing current or near-term healthcare AI, both as to function and sorting by ascending likelihood of mass adoption. Needless to say, the categories discussed below will exhibit considerable overlap.

*Administrative.*

There is urgent need to substitute out current healthcare administrative practices and technologies. According to CMS Administrator Seema Verma, "Healthcare remains in a 1990s time warp."[31] Indeed, healthcare administration was adversely impacted by the last healthcare technology shift: EHR adoption.

28. *See generally* AJAY AGRAWAL, JOSHUA GANS & AVI GOLDFARB, PREDICTION MACHINES: THE SIMPLE ECONOMICS OF ARTIFICIAL INTELLIGENCE 14-15 (Harvard Business Rev. Press 2018) (ebook).

29. JAMES MANYIKA ET AL., MCKINSEY GLOBAL INST., A FUTURE THAT WORKS: AUTOMATION, EMPLOYMENT, AND PRODUCTIVITY 23 (2017), https://www.mckinsey.com/~/media/mckinsey/featured%20insights/Digital%20Disruption/Harnessing%20automation%20for%20a%20future%20that%20works/MGI-A-future-that-works-Executive-summary.ashx.

30. EXEC. OFFICE OF THE PRESIDENT, ARTIFICIAL INTELLIGENCE, AUTOMATION, AND THE ECONOMY 18 (2016), https://obamawhitehouse.archives.gov/sites/whitehouse.gov/files/documents/Artificial-Intelligence-Automation-Economy.PDF.

31. Susan Morse, *CMS Administrator Seema Verma Calls for an End to Physician Fax Machines by 2020*, HEALTHCARE IT NEWS (Aug. 6, 2018), https://www.healthcareitnews.com/news/cms-administrator-seema-verma-calls-end-physician-fax-machines-2020.

One of the negative impacts that came with HER adoption was the shift of administrative tasks to physicians, resulting in workforce misalignment.[32] In the words of Atul Gawande, "I've come to feel that a system that promised to increase my mastery over my work has, instead, increased my work's mastery over me."[33] Thanks to AI, hospital and physician offices will see the increased use of "robotic process automation."[34] designed to automate routine or mundane office tasks such as making appointments, billing patients, and requesting reimbursement.[35] Natural language processing and digital assistants should improve note-taking and decrease the use of the main EHR "hack", the use of scribes[36] The next stage will be face identification for patient check-in.[37] AI analytics eventually will take over other tedious administrative tasks from humans including optimizing work force deployment, reducing readmissions while improving outcomes,[38] identifying high risk patients,[39] keeping referrals within network,[40] and combating fraud.[41]

*Custodial*

In much the same way that persons fulfill basic administrative tasks like billing, hospital custodial staff engage in repetitive or mundane tasks. Increasingly, healthcare facilities will replace many of their custodial staff with service robots such as the driverless vehicles that pull laundry and other carts around healthcare

32. See Jennifer Adaeze Okwerekwu, *Working at the 'Top of My License' Means I Sometimes Have To Say No*, STAT NEWS (Apr. 28, 2017), https://www.statnews.com/2017/04/28/doctors-license-training.

33. Atul Gawande, *Why Doctors Hate Their Computers*, NEW YORKER (November 12, 2018), https://www.newyorker.com/magazine/2018/11/12/why-doctors-hate-their-computers.

34. Steve Lohr, *'The Beginning of a Wave': A.I. Tiptoes Into the Workplace*, N.Y. TIMES (Aug. 5, 2018), https://www.nytimes.com/2018/08/05/technology/workplace-ai.html.

35. *Cf.* Alastair Gale and Takashi Mochizuki, *Robot Hotel Loses Love for Robots*, WALL ST J. (Jan. 14, 2019), https://www.wsj.com/articles/robot-hotel-loses-love-for-robots-11547484628 (noting that automated hotel is laying off its low-performing robots)

36. See Katie Hafnerjan, *A Busy Doctor's Right Hand, Ever Ready to Type*, N.Y. TIMES (Jan. 12, 2014), https://www.nytimes.com/2014/01/14/health/a-busy-doctors-right-hand-ever-ready-to-type.html.

37. Liang Chenyu, *Zhejiang Hospital Scans Faces to Register Patients*, SIXTH TONE (Oct 16, 2018), http://www.sixthtone.com/news/1003064/zhejiang-hospital-scans-faces-to-register-patients.

38. *The Crimson™ Technology Suite*, ADVISORY BOARD, http://www.advisory.com/Technology/Crimson (archived at http://web.archive.org/web/20170710171838/https://www.advisory.com/technology/crimson). *See generally* Anna Wilde Mathews, *Hospitals Prescribe Big Data to Track Doctors at Work*, WALL ST. J. at A1, July 11, 2013; *Rx to Avoid Health-Law Fines*, WALL ST. J. (Aug. 7, 2013), http://online.wsj.com/article/SB10001424127887323838204578654152046151798.html.

39. Haas LR et al, *Risk-stratification methods for identifying patients for care coordination*. 19 AM J MANAG CARE. 725, 725-32 (2013).

40. *Crimson Medical Referrals*, ADVISORY BOARD, https://www.advisory.com/technology/crimson-medical-referrals (archived at http://web.archive.org/web/20190120021342/https://www.advisory.com/technology/crimson-medical-referrals).

41. Roger Foster, *Top 9 Fraud and Abuse Areas Big Data Tools Can Target*, GOVERNMENT HEALTH IT (May 14, 2012), http://www.govhealthit.com/news/part-3-9-fraud-and-abuse-areas-big-data-can-target.

facilities,[42] food service, [43]machines that clean rooms of healthcare associated infections,[44] and automated pharmacy storage and retrieval systems.[45] Administrative, clinical, and custodial domains increasingly will share their data. For example, an AI administrative system should be able to combine outpatient appointment data, check-in data and data about visit lengths, cross-check local travel conditions, and accurately predict and control patient flow and workforce requirements. Such a system should enable another "hack," waiting-rooms, our current "imperfect solutions to uncertainty," to be eliminated.[46]

*Mobile Medical Apps, Wearables, and Chatbots*

Apps and wearables on mobile software platforms are established consumer technologies with their own evolving typologies[47] and regulatory challenges.[48] Currently, they function less as substitutes and more as an additional layer of technology, for example allowing patients to securely curate their own health records.[49] However, as their sensors and analytical software become more sophisticated, they will increasingly supplant professional early warning or diagnostic tasks[50], particularly as they integrate more fully with networked environmental sensors.[51] Their importance will be further elevated in the monitoring of chronic diseases and collecting data for clinical trials. Related to apps are chatbots, AI-based diagnostic triage systems that use language parsing coupled with searches of large databases to correlate symptoms and conditions. Subsequently, they make rule-based recommendations for an OTC remedy or make a physician referral.[52]

42. *See, e.g.*, Matt Simon, *Meet Tug, the Busy Little Robot Nurse Will See You Now*, WIRED (Nov. 10, 2017, 8:00 AM), https://www.wired.com/story/tug-the-busy-little-robot-nurse- will-see-you-now.

43. Josh Constine, *Taste Test: Burger Robot Startup Creator Opens First Restaurant*, TECHCRUNCH (June 21, 2018), https://techcrunch.com/2018/06/21/creator-hamburger-robot (discussing automated restaurant).

44. *See, e.g.*, *Why Choose Xenex?*, XENEX, http://xenex.com/about-xenex.

45. *See, e.g.*, *BoxPicker® Automated Pharmacy Storage System*, SWISSLOG, https://www.swisslog.com/en-us/healthcare/products/medication-management/boxpicker-automated-pharmacy-storage-system.

46. *See* AGRAWAL, GANS & GOLDFARB, *supra* note 28, at 105-06 (discussing aircraft lounges).

47. *See, e.g.*, Nicolas Terry & Lindsay F. Wiley, *Liability for Mobile Health and Wearable Technologies*, 25 ANNALS OF HEALTH LAW 62, 66-70 (2016).

48. *See, e.g.*, Terry, *supra* note 8, at 168-73.

49. *See, e.g.*, *iOS Health*, APPLE, https://www.apple.com/ios/health.

50. *See, e.g.*, Simon Brandon, *A Smartwatch Just Saved a Man from Having a Heart Attack*, WORLD ECON. F. (Oct. 20, 2017) https://www.weforum.org/agenda/2017/10/smartwatch-saved-man-from-heart-attack.

51. *See generally* Nicolas Terry, *Will the Internet of Things Transform Healthcare?*, 19 VAND. J. ENT. & TECH. L. 327 (2017).

52 Douglas Heaven, *Your Next Doctor's Appointment Might Be With an AI*, MIT TECH. REV. (Oct. 16, 2018), https://www.technologyreview.com/s/612267/your-next-doctors-appointment-might-be-with-an-ai.

*Caregiving*

AI will substitute for a broad category of family and professional caregiver functions.[53] The technology will range from something as simple as a "robotic" crib designed to help a baby sleep better,[54] to voice companions such as ElliQ that engage seniors in conversations and quizzes[55], to simple robot companions for elderly persons such as Palro[56], to robots such as RIBA that can lift and carry a person.[57]

*Research and Education*

Increasingly, pharmaceutical manufacturers are turning to AI to accelerate their drug development, primarily by searching for patterns in clinical data.[58] Routinely collected health data such as EHR data that was not initially collected for research purposes, together with data collected from wearables, is being used to train research AI. Furthermore, medical education will require fewer standardized or simulated patients[59] as robot patient simulators increasingly will exhibit "natural" symptoms and react to stimuli,[60] including AI simulations designed to teach empathy.[61] Longer term (but probably on a shorter time frame in less developed countries), AI may fundamentally change medical education; with the AI increasingly substituting for professionalism, the question will arise as to whether the provider, the user of the AI, needs to be highly trained in advance or whether we will reach the stage of point of care learning.[62]

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53. For a detailed treatment see VALARIE K. BLAKE, REGULATING THE MEDICAL ETHICS OF CARE ROBOTS, forthcoming.

54. Samantha Murphy Kelly, *A Robotic Crib Rocked My Baby to Sleep for Months*, CNN BUSINESS (August 10, 2017), https://money.cnn.com/2017/08/10/technology/gadgets/snoo-review/index.html.

55. ELLIQ, https://elliq.com.

56. PALRO, https://palro.jp/en/case.

57. Devin Coldewey, *Japanese Caretaker Robot to Assist in Lifting the Elderly*, TECHCRUNCH (Aug. 2, 2011), https://techcrunch.com/2011/08/02/japanese-caretaker-robot-to-assist-in-lifting-the-elderly.

58. Casey Ross, *Bristol-Myers Squibb Turns to an AI Startup to Accelerate Cancer Research*, STAT (Mar. 28, 2019), https://www.statnews.com/2019/03/28/bristol-myers-squibb-concerto-artificial-intelligence.

59. *See generally Standardized Patient for Teaching and Assessment*, JOHNS HOPKINS MEDICINE SIMULATION CENTER, https://www.hopkinsmedicine.org/simulation_center/training/standardized_patient_program/index.html.

60. *See, e.g.*, Sofia Lekka Angelopoulou, *Meet HAL, the Robot Child Capable of Bleeding, Yawning and Expressing Pain*, DESIGNBOOM (Sept. 9, 2018), https://www.designboom.com/technology/pediatric-hal-robot-patient-simulator-gaumard-09-08-2018.

61. Aili McConnon, *Virtual Simulations Offer a Cure to Doctors' Poor Bedside Manner*, WALL ST. J. (Apr. 1, 2019, 9:31 P.M. EST), https://www.wsj.com/articles/virtual-simulations-offer-a-cure-to-doctors-poor-bedside-manner-11554168671.

62. Shantanu Nundy & Michael L. Hodgkins, *The Application of AI to Augment Physicians and Reduce Burnout*, HEALTH AFF. BLOG (September 18, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180914.711688/full.

*Clinical Data Analytics*

Whether used for research or to train clinical AI, data analytics is increasingly important in healthcare. Indeed, "The market for storing and analyzing health information is worth more than $7 billion a year", attracting major technology companies such as Alphabet, Amazon, and Apple.[63] As the analytics engines become more powerful their roles, they will evolve from descriptive to diagnostic to predictive. At some point the analytics likely will turn prescriptive, with the AI itself deciding to execute a task.[64] As the amount of data that is fed into AI increases, so generally does its predictive abilities. Many of the most important breakthroughs therefore depend on feeding AI. For example, one proof of concept study used almost one quarter of a million electronic patient records, including clinical notes from two different hospitals and a total of almost 47 billion data points, and achieved high accuracy in predicting in-hospital mortality, unplanned readmissions, prolonged stay, and final discharge diagnoses.[65]

*Imaging, Pathology and Radiology*

It has been estimated that AI imaging will be a $2 billion business by 2023.[66] AI is particularly adept at pattern recognition, making it a natural fit for reading scans.[67] For example, it has been used to detect skin cancer,[68] colon cancer,[69] evidence of stroke,[70] and pneumonia.[71] Researchers have used Alphabet's DeepMind to develop a deep learning algorithm for examining three-dimensional optical tomography scans.[72] Panels of radiologists and pathologists are often asked to perform reads of scans; however, in a recent challenge competition, 7 deep

63. Melanie Evans & Laura Stevens, *Big Tech Expands Footprint in Health*, WALL ST. J. (Nov. 27, 2018), https://www.wsj.com/articles/amazon-starts-selling-software-to-mine-patient-health-records-1543352136.

64. *See, e.g.*, Chris Nott, *A Maturity Model for Big Data and Analytics*, IBM BIG DATA & ANALYTICS HUB (May 26, 2015), http://www.ibmbigdatahub.com/blog/maturity-model-big-data-and-analytics.

65. Alvin Rajkomar et al, *Scalable and Accurate Deep Learning with Electronic Health Records*, 1 NPJ DIGITAL MEDICINE Art. 18 (2018).

66. Simon Harris, *AI in Medical Imaging to Top $2 Billion by 2023*, SIGNIFY RESEARCH (Aug. 2, 2018), https://www.signifyresearch.net/medical-imaging/ai-medical-imaging-top-2-billion-2023.

67. *See, e.g.*, Andre Esteva et al., *Dermatologist-Level Classification of Skin Cancer with Deep Neural Networks*, 542 NATURE 115, 115 (2017); Dom Galeon, *AI-Assisted Detection Identifies Colon Cancer Automatically and in Real-Time*, FUTURISM (Oct. 30, 2017), https://futurism.com/ai-assisted-detection-identifies-colon-cancer-automatically-and-in-real-time/. *See also* John R. Zech et al., *Variable Generalization Performance of a Deep Learning Model to Detect Pneumonia in Chest Radiographs*: *A Cross-sectional Study*, 15 PLOS MED. e1002683 (2018), https://doi.org/10.1371/journal.pmed.1002683.

68. Esteva et al., *supra* note 67, at 115.

69. Galeon, *supra* note 67.

70. Charles J. Lynch & Conor Liston, *New Machine-learning Technologies for Computer-aided Diagnosis*, 24 NATURE MED. 1304, 1304-05 (2018).

71. *See also* Zech et al., *supra* note 67.

72. Jeffrey De Fauw, et al, *Clinically Applicable Deep Learning for Diagnosis and Referral in Retinal Disease*, 24 NATURE MED., 1342, 1342-1350 (2018).

learning algorithms showed greater discrimination than a panel of 11 pathologists.[73] Some of these technologies have resulted in commercial, FDA-approved products. For example, in 2017, the FDA approved Arterys, a cloud-based deep learning imaging platform[74] and in 2018 the FDA for the first time approved for sale AI algorithms; one designed to analyze two-dimensional x-rays to detect wrist fractures,[75] and another to diagnose diabetic retinopathy from retinal scans.[76] Another major platform, GE Healthcare's Critical Care Suite, is currently undergoing approval.[77]

*Predictive diagnosis*

There are many varieties of Clinical Decision Support (CDS) systems in use and, overall, they promote positive outcomes, notwithstanding their persistent flaws, such as alert fatigue.[78] However, the current generation of CDS is rule-based. Using AI will create far more powerful tools. Properly trained AI has the potential to dramatically improve diagnosis.[79] Its potential deserves emphasis, given that diagnostic errors effect five percent of U.S. outpatients annually, accounting for between six and seventeen percent of adverse events.[80] Examples include machine-learning algorithms that are vastly improving early predictions of

73. Ehteshami Bejnordi B, Veta M, Johannes van Diest P, et al., *Diagnostic Assessment of Deep Learning Algorithms for Detection of Lymph Node Metastases in Women with Breast Cancer*, 318 JAMA 2199, 2199–2210.

74. Bernard Marr, *First FDA Approval for Clinical Cloud-Based Deep Learning in Healthcare*, FORBES (Jan. 20, 2017), https://www.forbes.com/sites/bernardmarr/2017/01/20/first-fda-approval-for-clinical-cloud-based-deep-learning-in-healthcare/#3e51b1de161c.

75. Press Release, U.S. Food & Drug Admin., FDA Permits Marketing of Artificial Intelligence Algorithm for Aiding Providers in Detecting Wrist Fractures (May 24, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm608833.htm.

76. Press Release, U.S. Food & Drug Admin., FDA Permits Marketing of Artificial Intelligence-based Device to Detect Certain Diabetes-related Eye Problems (Apr. 11, 2018), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm604357.htm.

77. *Critical Care Suite on Optima XR240amx*, GE HEALTHCARE, https://www.gehealthcare.com/en/products/radiography/mobile-xray-systems/critical-care-suite-on-optima-xr240amx.

78. *See, e.g.*, Gilad J. Kuperman et al., *Medication-related Clinical Decision Support in Computerized Provider Order Entry Systems: A Review*, 14 J. AM. MED. INFORMATICS ASSOC. 29 (2007).

79. Editorial, *AI Diagnostics Need Attention*, 555 NATURE 285 (2018), https://www.nature.com/articles/d41586-018-03067-x.

80. INST. OF MED., IMPROVING DIAGNOSIS IN HEALTH CARE 1 (Erin P. Balogh et al. eds., 2015), https://www.nap.edu/catalog/21794/improving-diagnosis-in-health-care; *see also*, Daniel Morgan, *What the Tests Don't Show, Doctors are Surprisingly Bad at Reading Lab Results. It's Putting Us All At Risk*, WASH. POST (Oct. 5, 2018), https://www.washingtonpost.com/news/posteverything/wp/2018/10/05/feature/doctors-are-surprisingly-bad-at-reading-lab-results-its-putting-us-all-at-risk/.

diabetes and heart disease,[81] incipient dementia,[82] evidence of stroke,[83] determining whether colorectal polyps are merely benign,[84] and the health of embryos for in vitro fertilization treatment.[85] At a more pedestrian level, increasingly AI will also be incorporated in healthcare-related software, such as the analysis of emergency calls to detect cardiac arrest.[86] One of the broadest (and controversial[87]) applications has been *streams*, an algorithm running on Google's DeepMind that has been trained on more than a million patient records held by the Royal Free NHS Trust, that alerts clinicians about acute kidney disease in their patients.[88]

*Procedural AI*

As already noted, the current generation of surgical robots does not really deserve to be described as AI. Procedural aspects of medicine, particularly surgery, will likely remain in the human domain longer than other branches of medicine. Medium term we will see tiny robots injected into the body for targeted drug delivery as an alternative to surgery[89] and there have already been proof of concept studies on fully autonomous surgery robots.[90] The procedural domain has also seen its first controversy, when the FDA approved *Sedasys* automated anesthesia machine was withdrawn from the market after pushback from human anesthesiologists.[91]

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81. Yannis Paschalidis, *How Machine Learning is Helping Us Predict Heart Disease and Diabetes*, HARV. BUS. REV. (May 30, 2017), https://hbr.org/2017/05/how-machine-learning-is-helping- us-predict-heart-disease-and-diabetes.

82. Sulantha Mathotaarachchi et al, *Identifying Incipient Dementia Individuals Using Machine Learning and Amyloid Imaging*, 59 NEUROBIOLOGY AGING 80 (2017), https://doi.org/10.1016/j.neurobiolaging.2017.06.027.

83. Charles J. Lynch & Conor Liston, New Machine-learning Technologies for Computer-aided Diagnosis, 24 NATURE MED. 1304, 1304-1305 (2018), https://www.nature.com/articles/s41591-018-0178-4.

84. Galeon, *supra* note 67.

85. Jason Murdock, *Artificial Intelligence Boosts Chances of Successful IVF, Study Claims*, NEWSWEEK (Oct. 10, 2018), https://www.newsweek.com/artificial-intelligence-tech-helps-boost-chances-successful-ivf-study-claims-1161907.

86. *See, e.g.*, Khari Johnson, *Corti Heart Attack Detection AI Can Now Deploy on the Edge with Scandinavian Design*, VENTUREBEAT (Oct. 14, 2018), https://venturebeat.com/2018/10/14/cortis-heart-attack-detection-ai-can-now-deploy-on-the-edge-with-scandinavian-design.

87. Julia Powles & Hal Hodson, *Google DeepMind and Healthcare in an Age of Algorithms*, 7 HEALTH TECH. 351 (2017).

88. James Temperton, *DeepMind Hits Back at Criticism of its NHS Data-Sharing Deal*, WIRED (Nov. 22, 2016), http://www.wired.co.uk/article/deepmind-nhs-data-sharing-streams-app-privacy.

89. James Gorman, *This Tiny Robot Walks, Crawls, Jumps and Swims. But It Is Not Alive*, N.Y. TIMES (Jan. 24, 2018), https://www.nytimes.com/2018/01/24/science/tiny-robot-medical.html.

90. Azad Shademan et al, *Supervised Autonomous Robotic Soft Tissue Surgery*, 337 SCIENCE TRANSLATIONAL MED. 337ra64 (May 4, 2016), http://stm.sciencemag.org/content/8/337/337ra64.

91. Anthony Cuthbertson, *Plug Pulled on Robot Doctor after Humans Complain*, NEWSWEEK (Mar. 30, 2016), http://www.newsweek.com/plug-pulled-robot-doctor-after-humans-complain-442036.

### *B. Caveats about Substitution*

While substitution is an interesting rubric or at least an organizing concept, its value must not be overstated. As AI healthcare technologies are implemented, care will be needed lest substitution too heavily influences regulatory categories or determinations. For example, if an AI substitutes for a medical procedure, it does not necessarily follow that it is engaged in the "practice of medicine." Similarly, just because an AI substitutes for, say, an innocuous hospital food cart, that would not necessarily be determinative of the safety of the AI cart. As Ignacio Cofone notes, "If it looks like a dog, walks like a dog, and barks like a dog, it might still not be (like) a dog for normative purposes."[92] The regulatory determinations must be made on the basis of AI risks and benefits, not the risks and benefits of what they substituted for.

Substitution also requires context. Industrialized countries will tend to value patient-facing diagnostic or chronic care apps and wearables in terms of convenience, a substitute for visiting traditional brick-and-mortar care facilities. However, those in third world countries are more likely to embrace them, not as substitutes but as otherwise unobtainable healthcare.[93] There, bots and apps may constitute the first organized healthcare with broad availability, while also radically improving medical education and access to care.[94] Ironically, these worlds may see some merger (thereby supporting the reverse innovation theory[95]) as stressed first world healthcare systems try to meet demand with bots and apps. For example, the UK's NHS has begun to integrate services such as Babylon Health.[96] Some of these technologies are also targeted at underserved specialties such as behavioral health. For example, Marigold Health provides app-based support groups that are monitored both by care managers or peers and by an AI system that performs "sentiment analysis" to triage care.[97]

Finally, substitution may have time-limited relevance for typing AI. Start with the question, why would a human build an automated process or a robot? Logically, it would be to substitute for a human process. This is true for neural networks, enabling computational photography in our phones, robot vacuum

92. Ignacio N. Cofone, *Servers and Waiters: What Matters in the Law of A.I.*, 21 STAN. TECH. L.R. 167, 176 (2018).

93. James G. Kahn, Joshua S. Yang & James S. Kahn, *'Mobile' Health Needs and Opportunities in Developing Countries*, 29 HEALTH AFF. 254 (2010), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0965.

94. *See, e.g.*, Jonathan Mayes & Andrew White, *How Smartphone Technology Is Changing Healthcare in Developing Countries*, J. GLOBAL HEALTH (Nov. 1, 2016), https://www.ghjournal.org/how-smartphone-technology-is-changing-healthcare-in-developing-countries.

95. *See generally* VIJAY GOVINDARAJAN AND CHRIS TRIMBLE, REVERSE INNOVATION: CREATE FAR FROM HOME, WIN EVERYWHERE (2012).

96. *See NHS*, BABYLON HEALTH, https://www.babylonhealth.com/nhs.

97. MARIGOLD HEALTH, https://www.marigoldhealth.com.

cleaners, military killer drones, or complex, algorithm-driven data analytics. We build and substitute because we want to improve performance, avoid drudgery or risk, or minimize time and expense. However, we build only *substitutes* because, putting science fiction aside, as humans we lack a knowledge base beyond human processes in the physical world. Although it suggests philosophically murky territory, there will be a time when non-substitution AI arrives. However, it is unlikely to be the product of humans. Just as AI machine learning permits the creation of "new" data from training and input data or algorithmic processes outside of human understanding, future AI will itself be built by AI.

## III. EXTANT REGULATORY MODELS AND THEIR LIMITATIONS

To a large extent the examination of healthcare AI regulation has concentrated on the applicability of FDA device regulation and the adequacy of our data protection laws. More recently, particularly as substitution rhetoric has taken hold, it has appeared on the radar of the state licensing boards.[98]

The key concepts of "[medical] device" and the "practice of medicine" are not formally linked. The former is a function of federal law and a component of device supply chain regulation, the latter an exercise of state police power regulating clinicians. The FDA also makes clear that it does not regulate the practice of medicine, such as how and which physicians can use a device.[99] Notwithstanding, the two regulatory systems do have interdependencies; for example, it is difficult to imagine the FDA granting approval for a surgical robot to be sold over the counter while some devices, such as contact lenses, require a prescription written by a state licensed provider.

This article takes the position that neither of these path-dependent touchstones are particularly useful or transparent in determining whether and under what conditions AI healthcare should be approved or distributed. Specifically, it is a core tenet of this article that we abandon or supplement medical "device" and the "practice of medicine" as regulatory touchstones for healthcare AI. This is not only because they are inadequate to process the risks and benefits associated with AI but also because both are outdated touchstones for regulatory models that fail to sufficiently appreciate the "fundamental intertwining of the human and the

98. *See, e.g.*, Fed. State Med. Boards, *FSMB Spotlight: Dr. Patricia King, Chair of FSMB Board of Directors*, YOUTUBE (Dec. 6, 2018) at 7:31, https://youtu.be/EPLCg_T0R20?t=451.

99. "The FDA cannot and does not recommend specific medical devices for use in any setting." U.S. Food & Drug Admin., Frequently Asked Questions About Home Use Devices, https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/ucm204898.htm. *See also* 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."); Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 350 (2001).

technological domains"[100] involved in AI healthcare.

Notwithstanding, this section begins with a basic sketch of FDA device regulation and medical licensure. It then explores additional regulatory and public and private ordering models that impact the implementation of healthcare AI.

### *A. Device Regulation*

The idea of medical device regulation is relatively new, having been introduced by the Medical Device Amendments Act of 1976.[101] Regulation (such as PMA or post-marketing surveillance) hinges on a lightly defined, functional threshold finding that the object of regulation is a "device"; something "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . or . . . intended to affect the structure or any function of the body of man . . . "[102]

The FDA regulatory process (based on "device") sweeps up anything from a tongue depressor to a robotic-assisted, minimally invasive surgical system.[103] As Nicholson Price explains, such a "piecemeal approach" when faced with rapidly developing technologies has resulted in problems of both overregulation and under regulation.[104] As a result, a real question arises as to whether the FDA can keep up with the rapid innovations in digital health and, particularly, in healthcare AI. [105]

Congress attempted to help out its primary healthcare regulator and its struggles with emerging technologies in the 21st Century Cures Act (Cures). Although Cures excluded some healthcare software from the definition of device,[106] most of the excluded application and apps (such as billing software and fitness trackers) were already the subject of sub-regulatory guidances indicating regulatory discretion. Furthermore, the legislation did not really solve the regulatory indeterminacy problem because there are carve-ins that could return some forms of software with risk profiles (and increasingly AI features) such as clinical decision software to regulated space.[107] The FDA therefore has once again had to resort to interpretative and clarifying sub-regulatory guidances. For example, the agency has issued new guidances on medical software[108] and

100. MASSIMO CRAGLIA ET AL., ARTIFICIAL INTELLIGENCE: A EUROPEAN PERSPECTIVE 55, https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/artificial-intelligence-european-perspective.

101. Pub. L. No. 94-295 (codified as amended in scattered sections of 21 U.S.C.).

102. 21 U.S.C. § 321(h) (2018).

103. *See, e.g.*, INTUITIVE SURGICAL, https://www.intuitive.com.

104. W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421, 451-57 (2017).

105. *See, e.g.*, Casey Ross, *Artificial Intelligence is Evolving Fast. Can the FDA Keep Up?*, STAT (May 25, 2018), https://www.statnews.com/2018/05/25/artificial-intelligence-can-fda-keep-up.

106. 21 U.S.C. § 360j(o) (2018).

107. 21 U.S.C. § 360j(o)2)(b) (2018).

108. U.S. Food & Drug Admin., Changes to Existing Medical Software Policies Resulting from Section

clinician-facing and patient-facing patient decision support software.[109]

In this regard consider IBM's Watson Health. Reportedly, IBM has lobbied Congress to exempt Watson from device regulation[110] and was in part behind the partial medical software deregulation contained in Cures[111] that resulted in the software exclusions already discussed. Presumably, IBM's position is that Watson falls within Cure's clinical decision support (CDS) software exemption because it assists physicians in diagnosis and treatment. However, as the AI improves, the strength of this argument inevitably will decrease. The Cures carve-in awaits such products at the point of AI primacy, the tipping points where the AI is going beyond "supporting or providing recommendations to a health care professional,"[112] or no longer enables "such health care professional to independently review the basis for such recommendations that such software presents."[113] For example, the FDA does not interpret the independent review requirement as met "if the recommendation were based on non-public information or information whose meaning could not be expected to be independently understood by the intended health care professional user."[114]

Although this article contains implicit and explicit criticisms of the FDA, it is clear that that under Scott Gottlieb, its Commissioner between 2017-19, the FDA pushed hard on several fronts to transform its regulatory processes and reset the difficult safety-innovation dichotomy it faces.[115] For example, in an April 2018 speech Gottlieb noted "AI holds enormous promise for the future of medicine" and that "we must also recognize that FDA's usual approach to medical product regulation is not always well suited to emerging technologies like digital health, or the rapid pace of change in this area. If we want American patients to benefit from innovation, FDA itself must be as nimble and innovative as the technologies we're

3060 of the 21st Century Cures Act https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf.

109. U.S. FOOD & DRUG ADMIN., CLINICAL AND PATIENT DECISION SUPPORT SOFTWARE: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm587819.pdf

110. Casey Ross & Ike Swetlitz, *IBM to Congress: Watson Will Transform Health Care, So Keep Your Hands Off Our Supercomputer*, STAT (Oct. 4, 2017), https://www.statnews.com/2017/10/04/ibm-watson-regulation-fda-congress/.

111. 21st Century Cures Act, Pub. L. No. 94-295 § 3060(a).

112. *Id.* (amending Section 520(o)(1)(E)(ii) of the FDC Act) (codified as amended in 21 U.S.C. § 360(o)(1)(E)(ii) (2018)).

113. *Id.* (amending Section 520(o)(1)(E)(iii) of the FDC Act) (codified as amended in (21 U.S.C. § 360(o)(1)(E)(iii) (2018)).

114. U.S. FOOD & DRUG ADMIN., CLINICAL AND PATIENT DECISION SUPPORT SOFTWARE: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 8 (2017), https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm587819.pdf; *see also* "Examples of CDS and Other Software Functions for Health Care Professionals that Remain Devices." *Id.* at 10-11.

115. *See generally* Nathan Cortez, *Digital Health and Regulatory Experimentation at the FDA*, 18 YALE J. HEALTH POL'Y L. & ETHICS __ (2019), 21 YALE J.L. & TECH. __ (2019).

regulating."[116]

The agency's *Digital Health Innovation Action Plan*[117] is multi-faceted and, to an extent, is dependent on building out internal expertise to deal with emerging technologies.[118] More substantively, it seems consistent with Nicholson Price's model of combining "more moderate up-front regulation . . . with robust postmarket surveillance to monitor the performance of algorithms in real-world settings."[119] The agency's pivot has some smaller components such as a liberalized risk-based approach to outputs from software disseminated by a drug manufacturer that accompanies a prescription drug.[120] However, the centerpiece of the *Innovation Action Plan* is the agency's Precertification (Pre-Cert) Program that aspires to better align regulatory and technology iteration cycles by using a surrogate for device approval based on certifying manufacturers and their safety-testing protocols that evidence "excellence."[121] The most recent iteration notes how "FDA's traditional approach for the regulation of hardware-based medical devices is not well-suited for the faster, iterative design and development, and type of validation used for software device functions."[122] The program is aimed at "Software as a Medical Device" (SaMD)[123] "which may include software functions that use artificial intelligence and machine learning algorithms.."[124]

A recent FDA Discussion Paper highlights the problems that lie ahead for traditional regulatory mechanism.[125] So far FDA cleared or approved AI/ML-based SaMD have used "locked" algorithms, suggesting that future changes to the algorithm would require additional review. However, as the agency points out, "not all AI/ML-based SaMD are locked; some algorithms can adapt over time… Following distribution, these types of continuously learning and adaptive AI/ML

116. Scott Gottlieb, Commissioner, Food & Drug Admin., Transforming FDA's Approach to Digital Health (Apr. 26, 2018), https://www.fda.gov/NewsEvents/Speeches/ucm605697.htm.

117. U.S. Food & Drug Admin., Digital Health Innovation Action Plan, 2017, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf.

118. Id at 1.

119. Price, *supra* note 104, at 458 (albeit without his "information-forcing" proposal).

120. U.S. Food & Drug Admin., Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments (2018), https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25206.pdf; *see generally* Dave Muoio, *Proposed Framework Lessens FDA's Regulatory Requirements for Prescription Drug Companion Apps*, MOBILEHEALTHNEWS (Nov. 19, 2018), https://www.mobihealthnews.com/content/proposed-framework-lessens-fdas-regulatory-requirements-prescription-drug-companion-apps.

121. U.S. Food & Drug Admin., Digital Health Software Precertification (Pre-Cert) Program https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/default.htm.

122. U.S. Food & Drug Admin., Developing a Software Certification Program: A Working Model, v.1.0 (Jan. 2019), at 6, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM629276.pdf.

123. *Id.*

124. Id at 10.

125 Docket No. FDA-2019-N-1185; Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback, 3 (2019), https://www.fda.gov/media/122535/download

algorithms may provide a different output in comparison to the output initially cleared for a given set of inputs." The FDA-proposed framework for these unlocked algorithms is somewhat based on the Pre-Cert program and would employ a "Total Product Lifecycle Regulatory Approach" requiring, for example, a risk-based protocol for the development of the algorithm and robust monitoring of its changes.[126]

While innovation may be promoted with accelerated approval timelines and expedited models such as Pre-Cert, concerns have been raised by the large numbers of recent device approvals. An AP study published in late 2018 argued that a new FDA policy of being "first in the world" to approve new devices that led to a tripling of annual approvals has relied on less rigorous studies while at the same time the issuance of safety warning letters has declined by eighty per cent.[127]

### *B. Licensure*

In the broadest sense it is arguable that AI "requires a licence to operate from the public, based on trustworthiness."[128] In the far narrower context, that of professional licensure, it may seem questionable whether the state boards that are responsible for the licensing and discipline of physicians and other clinicians have anything more than a tangential relationship with the regulation of healthcare AI. Certainly, the mere fact that reportedly a robot was capable of passing the national medical licensing examination in China[129] says little about the actual practice of medicine.

The touchstone for medical licensure is "the practice of medicine." In most states, this includes holding oneself out as authorized to practice medicine in a jurisdiction, prescribing or administering a drug, diagnosing or treating disease, illness, or condition, performing surgery, or rendering a medical opinion.[130] In general, practicing medicine without a license is illegal. Those who are licensed are subject to standards of professional conduct derived from both ethical (e.g., truthfulness and transparency) and legal codes (e.g., confidentiality and reasonable care) and to disciplinary sanctions in the case of their breach.[131]

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[126] Id, at 7-15.

127. Matthew Perrone, *At FDA, a New Goal, Then a Push for Speedy Device Reviews*, ASSOC. PRESS (Nov. 27, 2018), https://www.apnews.com/9f8ea03a4d324d1ba5585680d280804b

128. Hetan Shah, *Algorithmic Accountability*, 376 PHIL. TRANSACTIONS ROYAL SOC'Y 20170362 at 1(2018).

129. Dom Galeon, *For the First Time, a Robot Passed a Medical Licensing Exam*, FUTURISM (Nov. 20 2017), https://futurism.com/first-time-robot-passed-medical-licensing-exam.

130. FEDERATION STATE MED. BDS., ESSENTIALS OF A STATE MEDICAL AND OSTEOPATHIC PRACTICE ACT (2015), http://www.fsmb.org/siteassets/advocacy/policies/essentials-of-a-state-medical-and-osteopathic-practice-act.pdf (paraphrase). For a specific state code see IND. CODE ANN. § 25-22.5-1-1.1 (2018).

131. *See, e.g.*, Standards of Professional Conduct and Competent Practice of Medicine, 844 Ind. Admin. Code art. 5.

Perhaps surprisingly, medical licensure regulation does have salience here. First, the most direct claim of all could be made that some future (and likely diagnostic or procedural) AI constitutes the "practice of medicine" under state law, requires a license, and is subject to other board requirements that vary from state to state but may include matters such as records retention and confidentiality. Presumably courts will be faced with the argument

that licensing statutes tend to use "person" language, rather than refer to device or object.[132] The opposing argument likely will concentrate on the identifying the natural or legal person making use of the AI.

Second, there are legal and organizational concepts that are related to the practice of medicine touchstone that may have far more relevance. These include the corporate practice of medicine (CPM) doctrine and scope of practice issues. The CPM doctrine embraced by some states is a correlate to the practice of medicine doctrine in that it prohibits those who cannot be personally licensed, specifically corporations, from either practicing medicine or employing physicians to do the same.[133] The justifications for the continued existence of the doctrine are the maintenance of individual physician judgment and upholding the quality of care.[134] Presumably, healthcare AI would at some point transgress this rule and in some cases be unable to leverage a popular exception to the prohibition, that of being a licensed hospital.[135]

Another practice of medicine correlate is scope of practice; the extent the limits of practice determined by licensure or board certification. The implications for healthcare AI are twofold. First, questions are likely to arise as to what aspects of healthcare specific AI should be allowed to "practice," for example whether an algorithm or robot designed for one task could be used for another. Second, (although not endorsed here) scope of practice could be adapted to regulate healthcare AI. The scope of practice of nurse practitioners (NPs) varies depending on state.[136] Some jurisdictions allow NPs to diagnose and treat without any involvement from a physician. Others require different levels of physician involvement, from working within protocols or having samples of their work reviewed. A similar model could be imagined for the way licensed physicians and healthcare AI may interact. For example, an autonomous AI could be allowed to

132. *See, e.g.*, "Holding *oneself* out to the public" IND. CODE 25-22.5-1-1.1(a)(1) (2018) (emphasis added).

133. *See generally* D. Cameron Dobbins, *Survey of State Laws Relating to the Corporate Practice of Medicine*, 9 HEALTH LAW., 1997, at 18.

134. *Corporate Practice of Medicine*, MED. BOARD. CAL., http://www.mbc.ca.gov/Licensees/Corporate_Practice.aspx (last visited Nov. 5 2018) ("The policy . . . is intended to prevent unlicensed persons from interfering with or influencing the physician's professional judgment.").

135. 49 PA. CODE §25.214 (2018).

136. *See generally Nurse Practitioner Scope of Practice Laws*, KAISER FAMILY FOUND., https://www.kff.org/other/state-indicator/total-nurse-practitioners.

treat certain diseases or administer certain treatments so long as it was under physician supervision or acting within physician-set guardrails.

Third, and a related concept: assuming that state medical boards do not regulate healthcare AI, they will be interested in how physicians interact with healthcare AI just as currently they are interested in physician-NP interprofessional collaboration and co-management of patient populations.[137] The boards will likely assert ethical supervision of such relationships, watching for conflicts of interest, breach of confidentiality, etc. Boards are also likely to be invested in physician primacy. This is not a particularly new issue, an earlier context being the accelerated implementation of CDS. There the issue has been framed as one of physician autonomy—whether the physician should comply with received alerts.[138]

Finally, although not strictly regulatory, organized medicine exerts considerable lobbying weight. The state boards, their national association (the Federation of State Medical Boards), the AMA and other professional organizations are powerful stakeholders that will influence the regulation of healthcare AI. Many members of the profession will welcome a new age of medicine. However, as with just about every attempted healthcare disruption or even more gentle reforms, some healthcare stakeholders will have no incentive to change. For others, adoption of AI or robotics will be welcomed only if it does not weaken their incumbent positions or their reimbursement. Given the potential for economic or other objections there is the risk that some board members may leverage their licensure and disciplinary powers to protect their own or their colleagues' income streams even though the technologies have become safer or new alternative technologies are available. There are historic examples such as the distribution of contact lenses,[139] other products that are sold inexpensively over-the-counter (OTC) outside the U.S.,[140] and telemedicine.[141] If, when dominated by market participants, boards do stray into such territory, antitrust laws likely will be invoked under the guidelines established by the Supreme Court in *North Carolina*

137. *See generally* AM. COLLEGE OBSTETRICIANS GYNECOLOGISTS, COLLABORATION IN PRACTICE IMPLEMENTING TEAM-BASED CARE 17-20 (2016).

138. David W. Bates et al., *Ten Commandments for Effective Clinical Decision Support: Making the Practice of Evidence-based Medicine a Reality*, 10 J. AM. MED. INFORMATICS ASS'N 523 (2003), https://academic.oup.com/jamia/article/10/6/523/760582.

139. Christopher Versace, *The FTC Finally Sees the Light on Contact Lenses*, FORBES (Jan. 17, 2017), https://www.forbes.com/sites/chrisversace/2017/01/17/the-ftc-finally-sees-the-light-on-contact-lenses/#337a724a6dde.

140. *See, e.g.*, Elisabeth Rosenthal, *When a Health Journalist Walks into a Pharmacy . . .* , MEDIUM (July 24, 2017) https://medium.com/@RosenthalHealth/when-a-health-journalist-walks-into-a-pharmacy-6cb60b519b5c.

141. *See, e.g.*, Jessica Davis, *Teladoc Drops Texas Lawsuit as State Adopts New Telemedicine Regulation*, HEALTHCARE IT NEWS (Dec. 04, 2017), https://www.healthcareitnews.com/news/teladoc-drops-texas-lawsuit-state-adopts-new-telemedicine-regulation.

*State Board of Dental Examiners v. FTC*.[142]

### *C. Privacy & Confidentiality*

Healthcare AI will join the pantheon of healthcare technologies such as mobile apps and big data that while promising much in the way of convenience, the reduction of friction, or efficiency have been dogged by concerns over their threat to the privacy of patient information. Inevitably, emerging technologies that share or process medical data will raise data protection concerns. However, the U.S. system is particularly challenged in the effectiveness of its responses.

U.S. data protection exhibits three fundamental flaws. First, it has been constructed using a sectoral approach, operationalized by the piecemeal introduction of discrete data protection regimes for different sectors or industries.[143] Second, these regimes favor somewhat conservative models of data protection that in general regulate how data custodians protect and use data (downstream protections) rather than data collection and retention (upstream protections).[144] Third, and a consequence of the first flaw, is that the different domain regulations are usually accompanied by a discrete regulator. Even where an exception to this model arises, such as the FTC's broad cross-sector jurisdiction,[145] it tends to be restricted by a distinctly narrow data protection mode, such as the FTC's Section 5 prohibition on "unfair or deceptive acts or practices,"[146] that in practice limits agency actions to parsing privacy policies or other representations by sellers[147] or dealing with repeat offenders.[148]

Data collected by AI or robots controlled by "covered entities" or their "business associates" (HIPAA entities) will in most cases be protected by the HIPAA Privacy, Security, and Breach Notification rules.[149] Those rules are enforced by a healthcare-specific regulatory agency, HHS-OCR.[150] In contrast, AI or robots controlled by non-HIPAA entities will benefit from a far more generous

142. 135 S. Ct. 1101 (2015) (state antitrust immunity limited in case of medical board market participants restricting teeth whitening services to licensed).

143. *See generally* U.S. DEP'T COM., COMMERCIAL DATA PRIVACY AND INNOVATION IN THE INTERNET ECONOMY: DYNAMIC POLICY FRAMEWORK, 60 (Dec. 2010), http://www.ntia.doc.gov/report/2010/commercial-data-privacy-and-innovation-internet-economy-dynamic-policy-framework.

144. *See generally* Nicolas Terry, *Regulatory Disruption and Arbitrage in Healthcare Data Protection*, 17 YALE J. HEALTH POL'Y L. & ETHICS 143 (2017).

145. 15 U.S.C. § 45(a) (2018) ("Affecting commerce.").

146. *Id.*

147. *See, e.g.*, Colleen Tressler, *FTC Presses Aura Over Blood Pressure App*, FED. TRADE COMM'N (Dec. 12, 2016), https://www.consumer.ftc.gov/blog/2016/12/ftc-presses-aura-over-blood-pressure-app.

148. *See, e.g.*, Press Release, Fed. Trade Comm'n, Wyndham Settles FTC Charges It Unfairly Placed Consumers' Payment Card Information At Risk, https://www.ftc.gov/news-events/press-releases/2015/12/wyndham-settles-ftc-charges-it-unfairly-placed-consumers-payment.

149. 45 C.F.R. Parts 160, 162, and 164 (2019).

150. *Office for Civil Rights (OCR)*, DEP'T HEALTH HUMAN SERV. https://www.hhs.gov/ocr/index.html.

data protection model. Entities in that space still will need to obey private party rules (such as app store or other distribution restrictions) and should stay well away from some highly specific regulatory regimes (such as credit reporting[151]). But otherwise, absent "unfair or deceptive acts or practices,"[152] their data practices will essentially be unregulated.[153] For example, if hospital laundry or pharmacy tugs and pickers or telepresence and caregiver robots incidentally capture patient data those data likely will be regulated by HIPAA. However, if the same or similar technologies were purchased by an individual on the consumer market (imagine the "Best Robot Buy" big box store of the future), HIPAA is unlikely to apply.

Given these uneven policy environments, an unnecessarily narrow view of data protection, and piecemeal enforcement, the key data protection problems raised by AI and robots are similar to those posed by the availability of mobile medical apps and the processing of medically-inflected data by data-brokers—regulatory disruption and arbitrage.[154] The disruption is caused by unmet expectations and indeterminacy. For example, privacy expectations that healthcare data is well-protected without any contextual exceptions are created by HIPAA privacy notices, while indeterminacy is caused by difficulty in identifying either regulation or regulator if HIPAA does not apply. The arbitrage is facilitated by data analytics entities being third parties with whom the patient or pre-patient has had no direct relationship and so no ability to assert (even limited) data protection rights; the data is being acquired from another entity (e.g., a supermarket record of the pre-patient's OTC purchases). The actual arbitrage is achieved by using non-HIPAA data or "laundered" HIPAA data to build healthcare data profiles outside of the HIPAA-regulated zone.[155]

### *D. Reimbursement*

In the U.S., perhaps more than any other country, the question of whether a healthcare technology will be implemented is as much dependent on whether its use will be reimbursed as it is on other more direct regulation. A classic example is telehealth which is finally showing potential for growth after the recent

151. *See, e.g.*, Press Release, Fed. Trade Comm'n, Texas Company Will Pay $3 Million to settle FTC Charges That It Failed to Meet Accuracy Requirements for Its Tenant Screening Reports, https://www.ftc.gov/news-events/press-releases/2018/10/texas-company-will-pay-3-million-settle-ftc-charges-it-failed.

152. 15 U.S.C. § 45(a) (2018).

153. Although outside of the scope of this article it should be noted that a few states have passed their own sometimes innovative privacy laws. Examples include Illinois' regulation of the collection of biometric information, Biometric Information Privacy Act, 740 ILCS 14/ and Alaska's protection of genetic privacy, Alaska Genetic Privacy Act S18.13.010-100. *See also* California's Consumer Privacy Act of 2018 discussed at text accompanying note 279.

154. *See generally* Terry, *Regulatory Disruption and Arbitrage in Healthcare Data Protection*, *supra* note 144.

155. *See generally* Nicolas Terry, *Big Data Proxies and Health Privacy Exceptionalism*, 24 HEALTH MATRIX 65 (2014).

announcement of Medicare reimbursement for home health remote patient monitoring.[156]

Of course, public and private payers are already users of sophisticated AI data mining systems designed to detect fraud and otherwise analyze provide performance, such as those authorized by the Medicare and Medicaid Program Integrity provisions of the Affordable Care Act.[157] However, payers may be less interested in reimbursing healthcare AI absent strong evidence of its cost-effectiveness or comparative effectiveness, vis-à-vis existing treatments.[158] Health insurer enthusiasm for healthcare AI must also be scrutinized because of how they may use the "lifestyle" data that they collect amid concerns that it is being used to cherry-pick healthier patients[159], notwithstanding the ACA's prohibitions on medical underwriting.[160]

In general, reimbursement is provided for "medically necessary" care and experimental treatments or devices are unlikely to be covered. Beyond that, reimbursement is a matter of policy and incentives. Of considerable interest is the October 2018 announcement by CMS recognizing "patients may experience unnecessary gaps between FDA approval of a technology and Medicare paying for the technology" and changes being made to the local coverage determination process[161] such that "coverage decisions will be more transparent and more responsive to innovators bringing new medical technologies to our Medicare beneficiaries."[162] Changes in CMS adoption of technologies is doubly important because private insurers often follow trends established by public payers.

### *E. Market Forces*

Related to regulation through reimbursement are general market forces. The healthcare technology market can be quite brutal. For example, there has been consistent negative reporting concerning IBM's Watson supercomputer. Having set its sights on becoming the preeminent cancer treatment system. "Watson for Oncology" appears to be struggling, both as to its capabilities and its implementation. Its once celebrated partnership between the MD Anderson Cancer

156. Press Release, Centers for Medicare & Medicaid Services, CMS Takes Action to Modernize Medicare Home Health (Oct. 31, 2018), https://www.cms.gov/newsroom/press-releases/cms-takes-action-modernize-medicare-home-health-0.

157. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 §6402 (codified as amended in 42 U.S.C. § 1320a-7k).

158. See discussion at text accompanying note 247.

159. Marshall Allen, *Health Insurers Are Vacuuming Up Details About You—And It Could Raise Your Rates*, PROPUBLICA (July 17, 2018), https://www.propublica.org/article/health-insurers-are-vacuuming-up-details-about-you-and-it-could-raise-your-rates.

160. 42 U.S.C. § 300gg (2018).

161. *See generally Medicare Coverage Determination Process*, CMS.GOV (Mar. 6, 2018), https://www.cms.gov/Medicare/Coverage/DeterminationProcess/index.html.

162. Seema Verma, *Modernizing Medicare to Take Advantage of the Latest Technologies*, CMS BLOG (Oct. 2 2018), https://www.cms.gov/blog/modernizing-medicare-take-advantage-latest-technologies.

Center and IBM to use the Watson platform for cancer research was put on hold after Watson reportedly after cost issues and a failure to meet its goals.[163] For example, it has been reported that the *Watson for Oncology* software often recommended erroneous cancer treatments, with internal studies suggesting that AI had not been trained on sufficient patient data or treatment guidelines.[164] Most tellingly, one report concluded that, despite the claims made for Watson, "the system doesn't create new knowledge and is artificially intelligent only in the most rudimentary sense of the term."[165] There are also reports that IBM is scaling back other parts of Watson Health business, such as helping hospitals manage pay for performance reimbursement because of reduced demand[166] and that the Watson division was laying off staff as it lost customers who were "fed up."[167] In large part, it appears that Watson has had difficulty developing technology to import clinical data such as that found in EHRs using natural language processing.[168] IBM has also been the subject of a particularly scathing report from an analyst suggesting that Watson was falling behind other technology companies in the deep learning space.[169]

It is arguable that other major players in healthcare AI are barely playing by market rules. For example, it was been reported that Google's DeepMind posted losses of $164 million in 2016 and $368 million in 2017. Essentially, big technology's healthcare AI projects are being subsidized by other parts of businesses at Amazon and Google. For example, Amazon's growing footprint in healthcare, for example developing at-home diagnostic products[170], is consistent with its corporate goal of extracting profit from all transactions and its own

163. Matthew Herper, *MD Anderson Benches IBM Watson in Setback for Artificial Intelligence in Medicine*, FORBES (Feb. 19, 2017, 3:48 PM), https://www.forbes.com/sites/matthewherper/2017/02/19/md-anderson-benches-ibm-watson-in-setback-for-artificial-intelligence-in-medicine/#50720f0f3774.

164. Casey Ross & Ike Swetlitz, *IBM's Watson Supercomputer Recommended 'Unsafe and Incorrect' Cancer Treatments, Internal Documents Show*, STAT (July 25, 2018), https://www.statnews.com/2018/07/25/ibm-watson-recommended-unsafe-incorrect-treatments.

165. Casey Ross & Ike Swetlitz, *IBM Pitched Its Watson Supercomputer As A Revolution In Cancer Care. It's Nowhere Close*, STAT (Sep. 5, 2017), https://www.statnews.com/2017/09/05/watson-ibm-cancer.

166. Casey Ross & Ike Swetlitz, *Citing Weak Demand, IBM Watson Health to Scale Back Hospital Business*, STAT (June 15, 2018), https://www.statnews.com/2018/06/15/ibm-watson-health-scale-back-hospital-business.

167. Casey Ross & Ike Swetlitz, *IBM's Problems with Watson Health Run Deeper Than Recent Layoffs, Former Employees Say*, STAT (June 11, 2018), https://www.statnews.com/2018/06/11/ibm-watson-health-problems-layoffs.

168. Casey Ross & Ike Swetlitz, *How an IBM Watson Health Rescue Mission Collapsed—and a Top Executive Was Ousted*, STAT (Nov. 1, 2018), https://www.statnews.com/2018/11/01/ibm-watson-health-natural-language-processing.

169. John Mannes, *Jefferies Gives IBM Watson a Wall Street Reality Check*, TECHCRUNCH (July 13, 2017), https://techcrunch.com/2017/07/13/jefferies-gives-ibm-watson-a-wall-street-reality-check.

170. Christina Farr & Eugene Kim, *Amazon Has Explored Getting Into Consumer Health Diagnostics—Testing For Disease At Home*, CNBC (Dec. 14 2018), https://www.cnbc.com/2018/12/14/amazon-explored-medical-diagnostics-was-in-talks-to-buy-confer-health.html.

healthcare ambitions.[171] Similarly, Google's collection and processing of clinical data may in part be designed to improve its search tools and so value to advertisers; one reason possibly behind its decision to directly manage DeepMind Health.[172]

Of course, markets themselves can be the subject of government regulation. This primarily occurs when there is market failure, of which there are several examples in healthcare technology space. In such cases, government will intervene to attempt to cure the failure. For example, in the late 1990s CMS mandated the healthcare industry to migrate to e-commerce platforms to achieve "Administrative Simplification."[173] Almost two decades later The Health Information Technology for Economic and Clinical Health Act of 2009 attempted to cure apparent market failure in the adoption of electronic health records (EHRs) with a subsidy model.[174] There are, therefore, levers other than reimbursement to build umbrella structures to facilitate data-sharing or to stimulate adoption if, for example, some AI application showed great promise to reduce public health costs but its poor return-on-investment made it unattractive to hospitals.

### *F. Litigation*

Almost inevitably healthcare AI will be touched by litigation. Injured patients will no doubt attempt to apply that state law liability doctrine to healthcare professionals, healthcare institutions, and healthcare AI developers.[175] Although involving a surgical teleoperation "robot" rather than true healthcare AI, the Supreme Court of Washington case *Taylor v. Intuitive Surgical, Inc.*,[176] is instructive as to the types of issues that may arise. A patient suffered injuries and later died following complications that arose during a robotic prostatectomy. Although the doctor was highly experienced in performing open prostatectomies, he had only performed two proctored procedures with the robot and the surgery in question was his first unproctored procedure. At trial, there was conflicting evidence about the level of training that should be required prior to an unproctored procedure, the question of the appropriateness of using the robot on a person with a high body mass index, and the role of the hospital in ensuring safe use of the device. The appeal was decided on a further issue, with the court holding that under

171. *See generally* Nicolas Terry, *"Prime Health" and the Regulation of Hybrid Healthcare*, 8 N.Y.U. J. INTELL. PROP. & ENT. L. 42 (2018).

172. Parmy Olson, *Why Google Just Tightened Its Grip on DeepMind*, FORBES (Nov 14, 2018), https://www.forbes.com/sites/parmyolson/2018/11/14/why-google-just-tightened-its-grip-on-deepmind.

173. *Administrative Simplification Overview*, CMS.GOV (Mar. 21, 2018), https://www.cms.gov/regulations-and-guidance/administrative-simplification/hipaa-aca/index.html.

174. Nicolas Terry, *Pit Crews With Computers: Can Health Information Technology Fix Fragmented Care?*, 14 HOUS. J. HEALTH L. & POLICY, 129, 160-64 (2014).

175. *See generally* Nicolas Terry & Lindsay F. Wiley, *Liability for Mobile Health and Wearable Technologies*, 25 ANNALS OF HEALTH LAW 62-97 (2016).

176. 187 Wash. 2d 743, 389 P.3d 517 (2017).

state product liability law the learned intermediary doctrine did not absolve the manufacturer from warning the hospital about risks associated with its products. *Taylor* puts several future issues on display. For example, which members of the distribution chain will face liability and under what legal theory and what are the relative responsibilities of hospitals and developers in training physicians and developing or enforcing protocols for the implementation of AI generally or its use in a particular case?

Other, more detailed issues, will need disposition. First, if robots are granted some level of social valence, a question might arise as to whether they have a direct relationship with the patient akin to the physician-patient relationship. Second, the scope of a human physician's responsibility in interacting with healthcare AI will be in play, again raising the question of the ultimate decisionmaker, clinician or AI (at least, until we reach the tipping point of AI primacy)?

Third, as healthcare institutions invest in AI, their own liability may shift. For example, traditionally hospitals have argued that they are not directly liable for the negligence of their independent contractor physicians who practice within their walls.[177] However, as those physicians are replaced or supplemented by AI, courts may view the healthcare as institutionally provided services and apply what is known as direct or corporate liability.[178] Additionally, litigation may itself be a driver of AI adoption if plaintiffs argue that the standard of care owed by hospitals necessitates the implementation of, for example, diagnostic algorithms.[179]

Fourth, courts are likely to face some very difficult doctrinal questions. For example, the question arises whether healthcare AI, particularly bare software algorithms, would be considered products for strict liability purposes given the Restatement's definition of a product as "tangible personal property distributed commercially for use or consumption."[180] The issue is complex and outside the scope of this article. However, it is at least arguable that non-custom software that causes physical damage is subject to strict liability.[181] Additional complications arise in the device space due to the preemption doctrine. In very general terms, state product liability claims regarding Class III medical device approved by the

177. *See, e.g.*, Sanchez v. Medicorp Health System, 270 Va. 299, 307-08 (2005), "[W]e have not previously imposed vicarious liability on an employer for the negligence of an independent contractor on the basis of apparent or ostensible agency, or agency by estoppel. We find no reason to do so in the specific context presented in this case." Cf. Kashishian v. Al-Bitar, 535 N.W.2d 105 (Wis. Ct. App. 1995) (liability for a non-employee physician based on apparent agency doctrine)

178. *See, e.g.*, Thompson v. Nason Hospital, 591 A.2d 703, 707-08 (Pa. 1991), "Today, we take a step beyond the hospital's duty of care delineated in [earlier case law] in full recognition of the corporate hospital's role in the total health care of its patients."

179. *See generally* Nicolas Terry, *When the Machine That Goes 'Ping' Causes Harm: Default Torts Rules and Technologically-Mediated Health Care Injuries*, 46 ST. LOUIS U.L.J. 37, 49-52 (2002).

180. Restatement (Third) of Torts: Products Liability § 19(a).

181. David Berke, *Products Liability in the Sharing Economy*, 33 YALE J. REG. 603, 609-18 (2016)

FDA through the PMA process are expressly preempted.[182] However, state law actions involving 510(k) devices, those approved on the basis of predicate device, generally are not preempted.[183] Of course, manufacturers of products that are not "devices" and so not subject to FDA regulation, such as (possibly) some custodial, caregiver, and companion robots, will not enjoy preemption arguments, and face strict liability.

Actions against the manufacturers of autonomous vehicles likely will act as canaries in the coalmine for healthcare AI liability. As the number of such vehicles increase so also have there been questions relating to their quality[184] and safety.[185] The inevitable litigation likely will establish an important new marker for when liability is imposed on the manufacturer rather than the driver. Healthcare AI litigation is potentially even more interesting as it has the potential to reallocate adverse event costs from physicians to healthcare entities and developers.

## IV. A MORE RESPONSIVE REGULATORY MATRIX

There are several touchstones for a new regulatory model for AI. First it must be unitary, not fragmented like today's medical device/practice of medicine duopoly. Second, it must be more holistic; any regulatory system must extend beyond quality, safety and efficacy with a broader consideration of inputs (e.g., transparency and data protection) and outputs (e.g., cost effectiveness and social impact).

Third, the regulation of AI should be universal and not domain specific. There are good arguments in favor of healthcare regulatory exceptionalism, from the protection required of particularly vulnerable populations through the sensitive nature of healthcare data.[186] However, the far-reaching implications of AI argue against any structures that would regulatory indeterminacy or arbitrage. Further, a domain agnostic model does not require that the specific ethical and legal needs of the healthcare domain should be ignored, only that the principles applicable to specific domains must be derived from and consistent with universal principles.[187] Fourth, a comment from the 2018 European Commission report is particularly instructive. While acknowledging the necessity of "avoiding detrimental or

182. Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), relying on 21 U.S.C. § 360k(a).

183. Medtronic v. Lohr, 518 U.S. 470, 492 (1996).

184. Laine Higgins, Dylan Moriarty & Jieqian Zhang, *The Bumps Ahead for Autonomous vehicles*, WALL ST. J. (Nov. 15, 2018), https://www.wsj.com/graphics/the-long-road-ahead-for-autonomous-vehicles.

185. Meriame Berboucha, *Uber Self-driving Car Crash: What Really Happened*, FORBES (May 28, 2018), https://www.forbes.com/sites/meriameberboucha/2018/05/28/uber-self-driving-car-crash-what-really-happened; Jake Lingeman, *Tesla Sued After Speed Limiter Removed, Passenger Killed in Fatal Crash*, AUTOWEEK (Jan. 11, 2019), https://autoweek.com/article/luxury/tesla-sued-after-speed-limiter-removed-passenger-dead-fatal-crash.

186. Terry, *Regulatory Disruption and Arbitrage in Healthcare Data Protection*, *supra* note 144, at 162-73.

187. This is the position taken by the GDPR—See Art. 9, Processing of special categories of personal data

unintended consequences, or guaranteeing that humans have control over their technologies", the report argued that such "externalist and instrumentalist perspectives tend to separate technologies from humans," viewing "technologies as mere neutral tools devoid of values, and humans as sole masters defining the terms of engagement.[188] Thus, future AI regulation must be contextually aware and responsive to what may be major shifts in the man-machine relationship. At the extreme, that analysis could change quite fundamentally if robots were granted any type of social valence. Finally, these regulatory changes must be made soon. One does not have to buy into the full dystopian vision of future AI to urge haste, merely that these changes need to be made before the point of AI primacy, when the AI takes over aspects of healthcare decision-making.

The construction of any new regulatory model must be based on generally accepted ethical and moral frameworks. The identification of those frameworks should include examination for how the frameworks can be validated and technologically infused into AI. The frameworks require supplementation with agreement over some broader questions; for example, the extent to which the data on which AI are trained and the data generated by AI are public goods and the protection of both individual and societal interests from surveillance and datafication. All of these frameworks are key. They also build to consideration of the final framework that consists of the elimination of discrimination, the promotion of health equity, and transparency. Together, these perhaps more than any other represent the battle for the "soul" of healthcare AI; whether like most traditional healthcare today it can be developed to be trustworthy and committed to beneficence or whether it will fuel the worst aspects of healthcare technocracy.

### *A. Normative Questions*

Building a responsive regulatory system begins with identifying the normative underpinnings. It is relatively easy to trot out familiar healthcare platitudes. Of course, we will want our AI to be inexpensive, promote well-being, and be patient-centric. Equally, there are enough affinities between healthcare's frequently misattributed "primum non nocere" [189] and Isaac Asimov's "Three Laws of Robotics" that we will not seriously debate hard-coded imperatives such as "A robot may not injure a human being" or "A robot must obey orders given it by human beings except where such orders would conflict with the First Law." [190]

However, both healthcare and AI involve normative challenges of far greater complexity. The tensions inherent in William Kissick's healthcare iron triangle

188. CRAGLIA ET AL., *supra* note 100, at 55.

189. Gonzalo Herranz, *Why the Hippocratic Ideals Are Dead*, 324 BMJ 1463 (2002), https://www.bmj.com/rapid-response/2011/10/29/origin-primum-non-nocere.

190. Isaac Asimov, *Runaround*, in I, ROBOT (1950).

(access, quality, and cost containment) are such that "Tradeoffs are inevitable regardless of the size of the triangle." [191] Healthcare policies and the laws that implement them continually make high-level distributional choices that have momentous implications for the well-being and even life of groups and individuals. And they reflect values that frequently fail broadly-held moral or ethical principles. For example, the U.S. healthcare system is generally unavailable for large swathes of the population, the poor who are too young for Medicare or above the meagre FPL limits for Medicaid. Even among the insured, those with better access to care, public and private policymakers impact individual well-being through the choices they make about dental or eye care coverage, drug-tiering, OOP expenses for hip or knee replacements, hospice coverage, etc. Not all of these choices are system-wide; some depend on geography and adversely impact persons who live in (primarily) Southern states that spend relatively little on healthcare and refuse to expand Medicaid. Other choices are not system-wide but are a function of individuals working in the system; mid-level administrators denying valid claims or clinicians allowing their implicit biases to affect the treatment provided to a patient of color. There are also likely to be disconnects over issues such as maximizing profit between those designing healthcare AI and those delivering care at the bedside.[192]

Healthcare AI like the humans it substitutes will have to deal with the healthcare system's chaotic multi-level choice architectures. An AI system designed to maximize value-based purchasing will make trade-offs as will a caregiver robot choosing which of its two chronically-ill patients to bathe first. Just as with the humans they substitute for, AI will make decisions that, downstream, impact access to or the quality of care. The question, therefore, is how do we program AI to make the "best" decisions, those that are aligned with our "best" moral and ethical principles?

This is, at least, a two-part inquiry. First, where do we find these moral and ethical principles? Second, after we convert these human normative values for machine use, how do we validate them such that patients and other non-policymaker stakeholders will trust our new medical machines?

AI ethical and moral principles (and here only a few examples can be given) have been advanced not only in innumerable statements of general applicability but also by stakeholders and researchers with specific health domain expertise.[193] As an example of the former, Google has published a series of "Objectives for AI

191. WILLIAM KISSICK, MEDICINE'S DILEMMAS: INFINITE NEEDS VERSUS FINITE RESOURCES, 2 (1994).

192. *See* Danton S. Char et al., *Implementing Machine Learning in Health Care—Addressing Ethical Challenges*, 378 NEW ENG. J. MED. 981 (2018).

193. *See, e.g.*, those referenced in CRAGLIA ET AL., *supra* note 100, at 45-51. *See also*, Sage, Building a competitive, ethical AI economy, http://www.sage.com/~/media/group/files/business-builders/ai-white-paper-aug2018.pdf?

applications," that include the avoidance of unfair bias and accountability.[194] IBM Research's AI Ethics group[195] has published AI principles based on Accountability, Value Alignment, Explainability, Fairness, and User Data Rights.[196] The company also has laid out guiding principles for AI deployment, (1) Purpose—to augment humans and be of service to them, (2) Transparency—how they were trained and with what data, and (3) Skills—building AI in partnership with persons with domain knowledge and training those in the domain to use the tools.[197]

In public policy space, the European Commission has classified AI challenges as manifesting at both individual and societal levels. Individual challenges identified include autonomy, identity, dignity, and data protection. Societal challenges included fairness and equity, collective human identity, responsibility, accountability and transparency, surveillance and datafication, democracy and trust, and the extent that collected knowledge should be viewed as a public good.[198] The Commission has recognized that the progression from these challenges to a new ethical framework for AI has lagged behind the technological developments but suggested two new "rights;" a right to choose "meaningful human contact" over robot contact and "the right to refuse being profiled, tracked, measured, analysed, coached or manipulated.[199]

In April 2019 the Commission's High-Level Expert Group on Artificial Intelligence published *Ethics guidelines for trustworthy AI*. The guidance took the position that "Only by ensuring trustworthiness will European individuals fully reap AI systems' benefits, secure in the knowledge that measures are in place to safeguard against their potential risks."[200] Trustworthy AI should be lawful, have an ethical purpose, and should be technically and socially robust (to better avoid unintentional harms).[201] The guidance expresses the concepts of ethical purpose and human-centric development as based on four principles or values; respect for human autonomy, prevention of harm, fairness and explicability..[202]

In the narrower healthcare domain, the AMA has published a policy guide on

194. Sundar Pichai, *AI at Google: Our Principles* (June 7, 2018), https://www.blog.google/technology/ai/ai-principles.

195. *Transparency and Trust in the Cognitive Era*, THINK BLOG (Jan. 17, 2017), https://www.ibm.com/blogs/think/2017/01/ibm-cognitive-principles.

196. ADAM CUTLER, LAWRENCE HUMPHREY & MILENA PRIBIĆ, EVERYDAY ETHICS FOR ARTIFICIAL INTELLIGENCE 8 (2018), https://www.ibm.com/watson/assets/duo/pdf/everydayethics.pdf

197. Alison DeNisco Reyome, *3 Guiding Principles for Ethical AI, from IBM CEO Ginni Rometty*, TECHREPUBLIC (Jan. 17, 2017), https://www.techrepublic.com/article/3-guiding-principles-for-ethical-ai-from-ibm-ceo-ginni-rometty.

198. CRAGLIA ET AL., *supra* note 100, at 56-60.

199. CRAGLIA ET AL., *supra* note 100, at 61-62.

200. EU DRAFT GUIDANCE ON AI, *supra* note 9 at 5.

201. *Id*.

202. *Id.* at 2.

healthcare AI.[203] In part, it seems less concerned about AI healthcare ethics and more about how the association sees its stakeholder role going forward; for example, it seeks to "Identify opportunities to integrate the perspective of practicing physicians into the development, design, validation and implementation of health care AI" and "Encourage education for patients, physicians, medical students, other health care professionals, and health administrators to promote greater understanding of the promise and limitations of health care AI."[204] Notwithstanding, the AMA's guide included some more actionable principles calling for AI that is transparent, reproducible, addresses bias, and "avoids introducing or exacerbating health care disparities including when testing or deploying new AI tools on vulnerable populations"[205]

Finally, representing bioethicists, Effy Vayena and colleagues have proposed that AI must satisfy three ethical concerns: that the data used complies with data protection requirements, that the AI development respects fairness by avoiding biased training data sets, and that the technology's deployment should satisfy transparency and avoid the "black box" problem.[206] Specifically with regard to this last the authors argue, "the disclosure of basic yet meaningful details about medical treatment to patients—a fundamental tenet of medical ethics—requires that the doctors themselves grasp at least the fundamental inner workings of the devices they use."[207]

A definitive synthesis of all these proposals is outside the scope of this article. However, issues such as transparency (and the related idea of reproducibility), avoidance of bias (both in the training data and in the algorithms), equity, cost-effectiveness, and data protection (privacy and security by design) are frequently mentioned. These seem to be appropriate underpinnings for addressing typical healthcare AI. However, as the healthcare AI field gets more specialized additional, context-sensitive constructs may need to be added to or derived from these general ethical and moral constructs; for example, to address specific ethical questions related to neuroengineering and human augmentation.[208]

A previous article argued that as AI healthcare data technologies become increasingly autonomous, we will have to address the possibility and desirability of programming ethical frameworks or artificial moral agents into the AI.[209] In that

203. AM. MED. ASS'N, AUGMENTED INTELLIGENCE IN HEALTH CARE (2018), https://www.ama-assn.org/press-center/press-release/ama-passes-first-policy-recommendations-augmented-intelligence.

204. *Id.*

205. *Id.*

206. Effy Vayena, Allesandro Blasimme & Glenn Cohen, *Machine Learning in Medicine: Addressing Ethical Challenges*, 15 PLOS MED. E1002689 (2018), https://doi.org/10.1371/journal.pmed.1002689.

207. *Id.* at 3.

208. Rafael Yuste et al, *Four Ethical Priorities for Neurotechnologies and AI*, 551 NATURE 159 (2017), https://www.nature.com/news/four-ethical-priorities-for-neurotechnologies-and-ai-1.22960.

209. *See generally* Colin Allen & Wendell Wallach, *Moral Machines: Contradiction in Terms or*

context I referenced the "Trolley Problem," the thought experiment that addresses how actors react to the relative worth of persons when a technology threatens life or serious injuries.[210] Recently there has been progress in programming AI to improve ethical and other hard choices. For example, Andrea Loreggia and colleagues have developed algorithms designed to check AI priorities against ethical principles,[211] while other IBM researchers have designed general purpose algorithms to audit systems for bias and mitigate same.[212]

Notwithstanding, there are important meta questions about any norms we embed in our AI. Whose norms or values, are they? For example, is it sufficient to canvas various governmental, industry, and academic stakeholders about how the machines should be programmed? The European Commission has been clear on the issue, "Ethical and secure-by-design algorithms are crucial to build trust in this disruptive technology, but we also need a broader engagement of civil society on the values to be embedded in AI and the directions for future development."[213]

Similarly, Edmond Awad and colleagues argue "even if ethicists were to agree on how autonomous vehicles should solve moral dilemmas, their work would be useless if citizens were to disagree with their solution, and thus opt out of the future that autonomous vehicles promise in lieu of the status quo.[214] Awad and his colleagues built a Moral Machine to assess social expectations about the ethical programming of autonomous vehicles. Various scenarios were imagined such as sparing many lives over fewer, the young over the elderly, men over women, etc.[215] The experiment attracted almost 40 million responses from over 200 countries. Some collected preferences differed markedly from ethical positions taken by regulators. For example, those surveyed showed a clear preference for saving the young, while regulators have tended to take a broad non-discriminatory approach including age.[216]

At some point the ethical choices programmed into healthcare AI will also require study and popular validation. Some of the questions likely could track the

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*Abdication of Human Responsibility*, in ROBOT ETHICS: THE ETHICAL AND SOCIAL IMPLICATIONS OF ROBOTICS 55 (Patrick Lin et al. eds., 2011).

210. Terry, *supra* note 8, at 173. *See also*, VALARIE K. BLAKE, REGULATING THE MEDICAL ETHICS OF CARE ROBOTS, forthcoming (discussing the ethical programming of caregiver robots).

211. Andrea Loreggia, et al, *Preferences and Ethical Principles in Decision Making*, *in* 2018 AAAI SPRING SYMPOSIUM SERIES (2018), http://www.aies-conference.com/wp-content/papers/main/AIES_2018_paper_74.pdf.

212. Kush Varshney, *Introducing AI Fairness 360*, THINK BLOG (Sept. 19, 2018), https://www.ibm.com/blogs/research/2018/09/ai-fairness-360. *See also* Rachel K.E. Bellamy et al, *AI Fairness 360: An Extensible Toolkit for Detecting, Understanding, and Mitigating Unwanted Algorithmic Bias*, ARXIV 180.01943 (2018), https://arxiv.org/abs/1810.01943.

213. CRAGLIA ET AL., *supra* note 100, at 13.

214. Edmond Awad, et al, *The Moral Machine Experiment*, 563 NATURE 59, 59 (2018), https://www.nature.com/articles/s41586-018-0637-6.

215. *Id.*

216. *Id.* at 60-61.

autonomous vehicle Moral Machine questions, e.g., the basic discrimination/non-discrimination norms. However, other health scenarios seem even more complex than the most challenging vehicle questions. For example, as Beatrice Hoffman has pointed out, the U.S. healthcare system rations by price, thereby discriminating against the poor.[217] Healthcare industry stakeholders have few incentives to change that model, but should this sad state be allowed to infect healthcare AI? How should the AI be programmed when its decisions may impact end-of-life care? And, perhaps most challenging, it is at least arguable that AI diagnostics will far outperform our present systems; begging the question whether their sensitivity should be "turned down" because we lack the healthcare resources to treat all those newly diagnosed conditions; potentially a troubling new form of healthcare rationing.

### *B. Societal Good and Public Goods*

It is an open question whether any U.S. debate over the regulation of healthcare AI can be expanded to include societal good and public goods issues. Increasingly these questions are being viewed as pivotal by policymakers in countries that have also embraced universal access and health equity. There, the use of healthcare system data by private parties may suggest stealth privatization. However, societal good and public goods arguments are less likely to achieve traction in a U.S. system that is built around private healthcare delivery and a mixed public-private financing model.

Although they are alluded to by some of the reports referenced above, the moral imperative of societal good and the ownership/excludability question posed by public goods deserve highlighting. Frankly, these are less obviously ethical questions and, more overtly, political ones. They implicate both the ownership of clinical data used to train AI and the data subsequently generated by the AI. The UK House of Lords Select Committee on Artificial Intelligence argued, "The data held by the NHS could be considered a unique source of value for the nation. It should not be shared lightly, but when it is, it should be done in a manner which allows for that value to be recouped."[218] Relatedly the GDPR provides, "The processing of personal data should be designed to serve mankind. The right to the protection of personal data is not an absolute right; it must be considered in relation to its function in society and be balanced against other fundamental rights, in accordance with the principle of proportionality."[219] In the U.S. these are starkly

217. BEATRIX HOFFMAN, HEALTH CARE FOR SOME: RIGHTS AND RATIONING IN THE UNITED STATES SINCE 1930, at 216 (2012).

218. SELECT COMMITTEE ON ARTIFICIAL INTELLIGENCE, AI IN THE UK: READY, WILLING AND ABLE?, 2017-19, HL 100, Ch 7 at ¶ 301, https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/100.pdf.

219. Commission Regulation 2016/679, Preamble 4, 2016 O.J. (L 119) 1.

challenging questions because, unlike many western industrialized countries,[220] the U.S. has not embraced the healthcare solidarity that typically underpins such discussions about societal good or healthcare data ownership.

In the private sector, Alphabet, Amazon, and Apple have all indicated an interest in closer integration of their technologies with clinical data, much of which comes from public sources. For example, Alphabet's DeepMind has a controversial relationship with a UK hospital trust giving it broad access to EHR data,[221] a relationship that caused additional concerns when Alphabet decided to integrate DeepMind into its Google division.[222] Amazon has released cloud-based software that can parse EHRs to provide data for analytics software.[223] Apple is reportedly in discussions with the Department of Veterans Affairs to make individuals' records available on Apple devices. Concerns about these public-private relationships are usually expressed in terms of data protection questions (e.g., if Google matched health records to Gmail emails). However, they should also be framed as public goods issues, as our clinical data is being used to generate private profit. Hetan Shah is correct in arguing that, in addition to transparency and other regulatory imperatives, "in the long run it will be the data which is the monopoly asset," and "the public sector should be more confident" in its negotiating power with AI companies.[224]

In the future AI may become the quintessential public health tool mapping out what we need to do to reduce social determinants of health and improve health equity.[225] Today, however, healthcare stakeholders are more likely to use these tools for more pedestrian, revenue-generating purposes such as reducing readmissions that otherwise would lead to Medicare readmission penalties or for public policy-avoiding, such as data mining to avoid health equity provisions in the ACA. Those involved in the highest levels of AI medical research may object to this characterization. For example, they might refer to the promise in AI for early for cancer diagnosis and personalized treatment. While that is literally true of the science, the motivation may be more complicated: cancer is big business,

220. *See generally* Richard B. Saltman, *Health Sector Solidarity: A Core European Value but with Broadly Varying Content*, 4 ISR. J. HEALTH POL'Y RES., no. 5, 2015.

221. *See, e.g.*, Alex Hern, *Royal Free Breached UK Data Law in 1.6m Patient Deal with Google's DeepMind*, GUARDIAN (July 3, 2017), https://www.theguardian.com/technology/2017/jul/03/google-deepmind-16m-patient-royal-free-deal-data-protection-act.

222. *Google Taking Over Health Records Raises Patient Privacy Fears*, BLOOMBERG (Nov. 21, 2018), https://www.bloomberglaw.com/document/X1DSQTFG000000.

223. Melanie Evans & Laura Stevens, *Big Tech Expands Footprint in Health*, WALL ST. J. (Nov. 27, 2018), https://www.wsj.com/articles/amazon-starts-selling-software-to-mine-patient-health-records-1543352136.

224. Shah, *supra* note 128, at 3.

225. Hutan Ashrafian & Ara Darzi, *Transforming Health Policy Through Machine Learning*, 15 PLOS MED. e1002692 (2018), doi:10.1371/journal.pmed.1002692; *see generally* Brad Bostic, *Using Artificial Intelligence to Solve Public Health Problems*, HEALTH IT & CIO REP. (Feb. 16, 2018), https://www.beckershospitalreview.com/healthcare-information-technology/using-artificial-intelligence-to-solve-public-health-problems.html.

and it creates major profit centers for hospitals[226] and drug companies.[227]

All may not be doom and gloom. For example, Google includes "Be socially beneficial" as the first of its "Objectives for AI applications."[228] It has also launched a competition called AI for Social Good, "a global call for nonprofits, academics, and social enterprises from around the world to submit proposals on how they could use AI to help address some of the world's greatest social, humanitarian and environmental problems."[229] Of course, a more dystopian interpretation of Google's policy can be found in Shoshana Zuboff's "surveillance capitalism" thesis,[230] which asserts that private actors will provide free access to advanced healthcare in exchange for all our health data that will then be used to train the AI and produce profitable predictive products.

### *C. AI Regulatory Design Objectives*

Building new regulatory criteria and processes for AI is a serious undertaking. For it to be worthwhile, there must be some clear design objectives. This framework must also be flexible, because both the benefits and risks of AI involve everything from the unforeseen to the unknowable. For example, it is possible that AI will accelerate beyond any human capacity to regulate it. The dystopian view is that this would mark not only a regulatory endpoint, but also, in the words of Nick Bostrom, "a technologically highly advanced society . . . which nevertheless lacks any type of being that is conscious or whose welfare has moral significance . . . A Disneyland without children."[231] Hopefully well in advance of that endpoint, a regulatory agency would either reverse course or allow the AI to regulate itself within human-programmed guardrails.[232]

At a more mundane level, the future regulation of healthcare AI will be better

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226. Shannon Brownlee, *Feeding the Cancer Machine*, N.Y. TIMES (Apr. 1, 2007), https://www.nytimes.com/2007/04/01/opinion/01brownlee.html; Kelly Gooch, *Hospitals See Growing 340B Profits on Cancer Drugs: 4 Findings*, HOSPITAL CFO REP. (Dec. 12, 2017), https://www.beckershospitalreview.com/finance/hospitals-see-growing-340b-profits-on-cancer-drugs-4-findings.html.

227. Jared S. Hopkins, *Merck's Blockbuster Cancer Treatment Powers Profit*, BLOOMBERG (July 27, 2018), https://www.bloomberg.com/news/articles/2018-07-27/merck-s-cancer-blockbuster-keytruda-powers-drugmaker-s-profit; Katherine Ellen Foley, *New Data Show that Cancer Drugs Cost Less to Make than Big Pharma has Claimed*, QUARTZ (Sept. 13, 2017), https://qz.com/1075285/new-data-show-that-cancer-drugs-cost-less-to-make-than-big-pharma-has-claimed/

228. Sundar Pichai, *AI at Google: Our Principles* (June 7, 2018), https://www.blog.google/technology/ai/ai-principles.

229. Jeff Dean & Jacquelline Fuller, *AI for Social Good*, GOOGLE (Oct. 29, 2018), https://www.blog.google/outreach-initiatives/google-org/ai-social-good.

230. Zuboff, Shoshana, *Big Other: Surveillance Capitalism and the Prospects of an Information Civilization*, 30 J. INFO. TECH. 75 (2015), doi:10.1057/jit.2015.5.

231. NICK BOSTROM, SUPERINTELLIGENCE: PATHS, DANGERS, STRATEGIES (2016) (ebook) at 173.

232. *Id.* at 185 ("endowing the AI with a final goal that corresponds to some plausible human notion of a worthwhile outcome"); *Id.* at 217 ("one could try to build an AI with the goal of doing what is morally right"); *see also* discussion at text accompanying notes 207-215.

served by abandoning some of our existing models. Gateways such as "medical device" fail to capture the cognitive sweep of healthcare AI, while its processes (such as §510(k)'s regulation by predicate) may perpetuate technological analogies of declining relevance. Similarly, it is important that we avoid re-using path dependent language such as the "practice of medicine" by trying to draw analogies to the scope of practice of doctors or nurse practitioners. Regulation should also try to avoid binary labelling (safe vs. unsafe) in favor of an explicitly holistic, multi-faceted inquiry that includes, for example, quality, safety, data protection, transparence, and so on.

Finally, and largely outside the scope of this article, attention will have to be paid to the identity and structure of the regulator. There have already been questions raised about whether the FDA could better avoid political pressure if it was established as an independent agency outside of HHS.[233] Similarly, an independent regulatory agency for AI may be the preferable solution. For example, Sandra Wachter and colleagues have argued for a "trusted third party" to audit AI for compliance with the EU right of explanation or, alternatively, for the creation of a regulator "specifically for auditing algorithms, before (certifications) and/or after algorithms are being deployed."[234] Of course, we may find ourselves getting sidetracked by debates over this "super-regulator" when energy could be better directed at improving substantive rules. If a super-regulator ends up being favored, then, as with the case of data protection,[235] the preferred solution would be to have a single AI regulatory agency, not a healthcare-specific one. Use of a single regulatory agency would help to avoid regulatory exceptionalism, indeterminacy, or arbitrage.

### *D. Regulatory Imperatives*

One of the core arguments in this article is that regulatory models that separately judge the safety of healthcare (such as by using current FDA "device" scrutiny) and police the conduct of medical professionals who interact with healthcare AI (as with "the practice of medicine") are conceptually ill-equipped to regulate future AI technologies. This section suggests that the better course is to adopt a holistic approach sensitive to how the technological and human domains are fundamentally intertwined. The recent EU Commission report on AI ethics suggested the following regulatory requirements; "(1) human agency and

233. Nicholas Florko, *Decrying Political Pressure at FDA, Former Commissioners Push a Breakaway Plan*, STAT (Oct. 19, 2018), https://www.statnews.com/2018/10/19/seven-former-fda-commissioners-think-the-agency-faces-too-much-political-pressure.

234. Sandra Wachter, Brent Mittelstad & Luciano Floridi, *Why a Right to Explanation of Automated Decision-making Does Not Exist in the General Data Protection Regulation*, 7 INT. DATA PRIVACY L. 76 (2017).

235. See discussion *infra*.

oversight, (2) technical robustness and safety, (3) privacy and data governance, (4) transparency, (5) diversity, non-discrimination and fairness, (6) environmental and societal well-being and (7) accountability."[236]

This is a workable list of regulatory priorities. They should be implementable in a non-binary fashion and seem well-suited to reflect different tradeoffs in diverse products and services (for example, one AI may require heightened safety, another high levels of transparency). Although all are interlinked and interdependent, clearly several of them (for example, privacy and transparency) are even more tightly intertwined. This section does not attempt a comprehensive examination of each imperative. Rather, a selection of imperatives is discussed in the context of healthcare AI, together with certain additional (or sometimes differently labelled or emphasized) suggestions for regulatory focus.

*1. Quality and Safety*

Overall, quality and safety imperatives are well-known and non-contentious. In all probability, the safety imperative can be appropriately addressed by something akin to the FDA's risk-based model.[237] For example, the agency recently published a caution letter warning that notwithstanding reports it had received of surgeons using robotically-assisted surgical devices in mastectomy procedures, neither the safety nor the effectiveness of those devices for such procedures had been established.[238] As a result, this section provides only a cursory examination of the quality and safety issues posed by healthcare AI.

In many high-risk domains, automation is either accepted (for example, commercial airplanes are flown more by auto-pilot than the flight crew[239]) or eagerly anticipated (for example, using autonomous vehicles to avoid accidents caused by driver errors[240]). Without reiterating all the potential beneficial uses for healthcare AI, immediate improvements can be imagined, from physicians being relieved of administrative tasks so that they can practice at the top of their licenses, to patients being able to self-manage their chronic diseases, to far earlier and more accurate diagnoses.

236. EU GUIDANCE ON AI, *supra* note 9, at 2.

237. See U.S. FOOD & DRUG ADMIN., MEDICAL DEVICE ENFORCEMENT AND QUALITY REPORT 3 (November 2018), https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM626352.pdf.

238. U.S. FOOD & DRUG ADMIN., CAUTION WHEN USING ROBOTICALLY-ASSISTED SURGICAL DEVICES IN WOMEN'S HEALTH INCLUDING MASTECTOMY AND OTHER CANCER-RELATED SURGERIES: FDA SAFETY COMMUNICATION (Feb. 28, 2019), https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm632142.htm.

239. Vinod Khosla, *Technology Will Replace 80% of What Doctors Do*, FORTUNE (Dec. 4, 2012), http://fortune.com/2012/12/04/technology-will-replace-80-of-what-doctors-do.

240. Aarian Marshall, *To Save the Most Lives, Deploy (Imperfect) Self-Driving Cars ASAP*, WIRED (Nov. 17, 2017), https://www.wired.com/story/self-driving-cars-rand-report.

The upside of these technologies is offset by two core quality and safety concerns. First, AI is, and increasingly will grow, beyond human understanding, often resulting in algorithms that are "fully opaque" or "so complex as to defy understanding."[241] Second, while robots seem relatively tame when they resemble cuddly seals or convenient digital assistants that remind you to refill your prescription, their offspring may combine, in the words of Ryan Calo, "the generative promiscuity of data with the capacity to do physical harm."[242]

While the similarities between quality and safety issues posed by AI and the issues posed by devices that traditionally been submitted to the FDA (or other risk-based agencies) for approval will not be labored, it is important to highlight some of the differences. First, quality and safety will depend not only on hardware and software behavior but, increasingly, on the data used to train the AI. According to the EU Commission, "Whilst ML is the generic class of algorithms that learn from the data, their accuracy depends very much on the quality of the training dataset, and how well they have been structured, semantically labelled, and cleaned by humans to make them representative of the problem to tackle, and reduce the number of parameters in the data."[243] Indeed, as noted by one healthcare AI research team, "The quantity and quality of the training set are critically important in the development of state-of-the-art deep learning . . . "[244]

Second, as the technology advances, the list of unique safety and quality issues involving healthcare AI will grow. For example, Robert Challen and colleagues have suggested a general framework for cataloging such issues. They identify, first, short-term issues such as "distributional shift," "insensitivity to impact," "black box decision making," and "unsafe failure mode." Second, they classify medium-term issues as "automation complacency," "reinforcement of outmoded practice," and "self-fulfilling prediction." Finally, they label long-term issues such as "negative side effects," "reward hacking," "unsafe exploration," and "unscalable oversight."[245] This typology may or may not prove to be definitive, but it seems inarguable that such risk identification research must proceed apace so as to inform healthcare AI design best practices and generate regulatory checklists.

*2. Efficacy and Cost-Effectiveness*

In addition to its safety inquiries, the FDA examines a device's efficacy, that

241. Price, *supra* note 104, at 435.

242. Ryan Calo, *Robotics and the Lessons of Cyberlaw*, 103 CAL. L. REV. 513, 534 (2015).

243. CRAGLIA ET AL., *supra* note 100, at 20.

244. Carolina Lugo-Fagundo, Bert Vogelstein, Alan Yuille & Elliot K. Fishman, *Deep Learning in Radiology: Now the Real Work Begins,* 15 J. AM. C. RADIOLOGY 364 (2018).

245. Robert Challen et al., *Artificial Intelligence, Bias and Clinical Safety*, 28 BMJ Quality & Safety 231, 234 tbl. 1 (2019).

is its effectiveness for a particular use.[246] Similarly, the FTC's scrutiny of device representations can include scientific efficacy, in that it can require randomized and controlled human clinical trials to substantiate a manufacturer's marketing claims.[247]

However, the agencies do not address comparative effectiveness (CER); how a device's effectiveness compares with an existing device or some other clinical intervention. Nor are devices subject to cost-effectiveness analysis or benchmarking (CEA). In this regard, the U.S. regulatory systems differ from the New Technology Assessment used by many other industrialized countries to determine, for example, whether a product should be included in a national formulary or at what price.[248]

At the very least, our conceptions of quality, safety, and data protection should reflect CER—and preferably CEA.[249] Once again, the debate over autonomous vehicles is illustrative. One of the primary arguments in favor of such vehicles is that they will eliminate almost all highway fatalities, given that ninety-four per cent of serious crashes involve human error. However, a deeper dive into the causes of those crashes and the limitations of autonomous vehicles suggest a far more modest number of lives will be saved.[250] Similar, and even intuitively accurate, claims are likely are likely to be made about the safety of healthcare AI, suggesting we will need robust data to help us make regulatory decisions.

Although exact timelines remain murky it seems likely that AI will have an enormous impact on our healthcare system, including physical (workforce) and intellectual (analysis including diagnostics) substitutions. Given how this will change investment priorities for both public and private bodies, the likely reinvestment of private and public moneys, and the general economic dislocation that is likely, benchmarking tools such as CER and CEA should have great salience. They should be applied on both a macro and micro basis, critically analyzing both industry-wide and device-to-device substitutions. In the case of the former, AI and robots are heralded as capable of automating drudgery and, as

246. U.S. Food & Drug Admin., FDA's Role in Regulating Medical Devices (Aug. 31, 2018), https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/ucm204884.htm.

247. *See, e.g.*, POM Wonderful, LLC v. FTC, 777 F.3d 478, 484–85 (D.C. Cir. 2015), *cert denied*, 136 S. Ct. 1839 (2016).

248. *What We Do*, NAT'L INST. FOR HEALTH & CARE EXCELLENCE, https://www.nice.org.uk/about/what-we-do; *Responsibilities and Objectives of IQWiG*, INST. QUALITY & EFFICIENCY IN HEALTH CARE, https://www.iqwig.de/en/about-us/responsibilities-and-objectives-of-iqwig.2946.html. *See also Health Technology Assessments Receive European Parliament Backing*, MED. PLASTICS NEWS (Oct. 4, 2018), https://www.medicalplasticsnews.com/news/european-parliament-backs-health-technology-assessments.

249. Terry, *Appification, AI, and Healthcare's New Iron Triangle*, *supra* note 8, at 123-24.

250. Alison Snyder & Joann Muller, *Why Driverless Cars Could Save Far Fewer Lives Than Expected*, AXIOS (Nov. 21, 2018), https://www.axios.com/driverless-cars-deaths-safety-limits-66dcd5da-2f0a-49aa-b097-aad5c7485c42.html.

Kevin Kelly notes, many of these are "jobs we could never do."[251] However, one person's drudgery is another's limited employment opportunity. Healthcare is a leading economic engine in the U.S., with healthcare jobs growing at around seven times the rate of the non-healthcare economy.[252] Although some of these jobs are for professionally-trained clinicians, the vast majority are for lower-skill administrators and hospital or home-based caregivers.[253] If these are supplanted by AI or robots, the negative impact on the healthcare economy will be substantial .[254]

Not surprisingly there have been proposals to use taxes to create funds for the re-education of economically exiled humans.[255] Thus, Microsoft co-founder Bill Gates has argued, that in certain cases taxes should be used to slow down the speed of automation while policymakers "manage that displacement."[256] Here, too, robust CER and CEA data should be able to guide policymakers in making any such decisions. For example, new technologies that make only marginal contributions yet have large displacing impact might be taxed more than a highly innovative AI that is similarly displacing but which substantially reduces healthcare costs.

*3. A Modern Data Protection Construct*

Data protection and freedom from surveillance parallel the question of societal good. They are issues that involve both individual and societal questions of great import. Again, these issues display considerable maturity in Europe, as evidenced by the recently implemented EU General Data Protection Regulation (GDPR).[257] In contrast, the debate about stronger data protection in the U.S. is nascent. However, a heavily modernized data protection construct is a *sine qua non* for trusted implementation of healthcare AI.

As noted above, the weaknesses of current U.S. data protection are its sectoral approach, outdated and primarily downstream data protection models, and the

251. Kevin Kelly, *Better Than Human: Why Robots Will–And Must–Take Our Jobs*, WIRED (Dec.24, 2012), https://www.wired.com/2012/12/ff-robots-will-take-our-jobs.

252. Edward Salsberg & Robert Martiniano, *Health Care Jobs Projected to Continue to Grow Far Faster Than Jobs in the General Economy*, HEALTH AFF. BLOG (May 9, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180502.984593/full.

253. *Id.*; Derek Thompson, *Health Care Just Became the U.S.'s Largest Employer*, ATLANTIC (Jan. 9, 2018), https://www.theatlantic.com/business/archive/2018/01/health-care-america-jobs/550079.

254. *See generally* Executive Office of the President (National Science and Technology Council), Artificial Intelligence, Automation, and the Economy, Dec. 2016, https://obamawhitehouse.archives.gov/sites/whitehouse.gov/files/documents/Artificial-Intelligence-Automation-Economy.pdf.

255. *See generally* James Walker, *San Francisco Could Start Taxing Robots to Save Jobs*, DIGITAL J. (Aug. 25, 2017), http://www.digitaljournal.com/tech-and-science/technology/san-francisco-could-start-taxing-robots-to-save-jobs/article/500931.

256. Kevin J. Delaney, *The Robot That Takes Your Job Should Pay Taxes, Says Bill Gates*, QUARTZ (Feb. 17, 2017), https://qz.com/911968/bill-gates-the-robot-that-takes-your-job-should-pay-taxes.

257. Commission Regulation 2016/679, 2016 O.J. (L 119) 1, https://eugdpr.org.

proliferation of domain-specific regulators. In general, healthcare data custodians that are not HIPAA covered entities or their business associates are regulated only lightly. While the data used to train AI and the data generated by AI are healthcare data, it is less likely that the data custodians or processors (e.g., app and wearable developers or large AI companies) will be HIPAA covered entities or even business associates. First, the data may be supplied by the data subjects themselves not their providers (as would be the case with many wearables). Second, the data may originate outside of the conventional healthcare such as when data brokers collect medically inflected data.[258] Third, even where AI companies enter into direct relationships with healthcare entities, they may avoid HIPAA regulation by collecting only deidentified data,[259] even though such companies are likely the best situated technologically to reidentify the data though triangulation.[260]

Currently, regulators are likely to show interest in data protection if data custodians adopt flagrantly poor security practices or fail to comply with their own privacy policies. As a matter of practice, these lightly regulated businesses have adopted a notice and consent (or choice) model of privacy "protection." Scholars such as Robert Sloan and Richard Warner have critiqued notice and consent as "neither free nor informed consent; nor does it yield an acceptable tradeoff."[261] Further, the manner in which data brokers acquire healthcare data, typically indirectly and not from the data subject,[262] renders any notice and consent process illusory. As Michael Froomkin argues, albeit in the context of human subject research, "Big Data kills the possibility of true informed consent because by its very nature one purpose of big data analytics is to find unexpected patterns in data."[263] This point is only amplified by the application of AI/ML to those data; not only will unexpected patterns be found but the AI may generate "new" unanticipated data such as when the AI uses probabilistic techniques such as Gaussian Processes.[264]

Newly emerged technologies such as app platforms, data analytics, and the Internet of Things[265] offer unprecedented challenges to the privacy and security of

258. See Terry, *Big Data Proxies and Health Privacy Exceptionalism*, *supra* note 155, at 84-87.

259. HIPAA Protected health information is individually identifiable health information transmitted or maintained by a covered entity or its business associates. 45 C.F.R. § 160.103 (2019).

260. *See generally* Boris Lubarsky, *Re-identification of "Anonymized" Data*, 1 Geo. L. Tech. Rev. 202 (2017), https://georgetownlawtechreview.org/re-identification-of-anonymized-data/GLTR-04-2017.

261. Robert H. Sloan & Richard Warner, *Beyond Notice and Choice: Privacy, Norms, and Consent*, 14 J. HIGH TECH. L. 370, 390 (2014).

262. Terry, *Regulatory Disruption and Arbitrage in Healthcare Data Protection*, *supra* note 144, at 178-79.

263. A. Michael Froomkin, *Big Data: Destroyer of Informed Consent*, 18 YALE J. HEALTH POL'Y L. & ETHICS __ (2019), 21 YALE J.L. & TECH. __ (2019).

264. *See generally* Zoubin Ghrahramani, *Probabilistic Machine Learning and Artificial Intelligence*, 521 NATURE 452 (2015), https://www.nature.com/articles/nature14541.

265. *See generally* Terry, *Will the Internet of Things Transform Healthcare?*, *supra* note 51.

data and the uses to which it is put. For example, location services used for tasks such as navigation or, in the health space, fitness tracking provide the opportunity for massive amounts of unconsented-to surveillance.[266] The emerging technologies discussed here provide more opportunities for the collection of sensitive data of data collection (healthcare robots) and immeasurably more powerful insights, including reidentification, from collected data (AI). Similar to mobile medical apps, AI and robots that are not tied to a HIPAA entity face little or no regulation as to how they should share data with third parties or the level of security they should provide.[267]

Apple CEO Tim Cook has warned, "Our own information — from the everyday to the deeply personal — is being weaponized against us with military efficiency."[268] The recent EU Guidance on AI ethics expressed considerable concern about the potential of AI to provide public and private entities with more efficient ways to identify individuals without their consent.[269] Other recognized threats include widespread surveillance, datafication or commoditization of persons, and more micro concerns such as undermining ACA protections against medical underwriting with big data facilitated drug tiering, or, more indirectly, the use of health scores by employers to make their workforce more attractive to health insurers.

AI and robots are also "always on." AI requires a constant feed of input data to process though its trained algorithms, while a caregiver robot's sensors (cameras, face recognition, voice recognition, radar, lidar, proximity, accelerometer, moisture, etc.) will continually process environmental and patient data. There are already concerns about the surveillance risks of "always on" personal digital assistants such as Amazon's Echo and Google Home.[270] The risks associated with AI and robots are at a completely different level. They are more akin to the facial and gait recognition employed in countries with high-level surveillance.[271]

Two questions are particularly pertinent in understanding the role of data protection in the regulation of AI: first, a procedural question as to the extent the

266. *See, e.g.*, Jennifer Valentino-DeVries, Natasha Singer, Michael H. Keller & Aaron Krolik, *Your Apps Know Where You Were Last Night, and They're Not Keeping It Secret*, N.Y. TIMES (Dec. 10, 2018), https://www.nytimes.com/interactive/2018/12/10/business/location-data-privacy-apps.html.

267. Terry, *Appification, AI, and Healthcare's New Iron Triangle*, *supra* note 8, at 137.

268 Natasha Lomas, *Apple's Tim Cook Makes Blistering Attack on the 'Data Industrial Complex*,' TECHCRUNCH (Oct. 24, 2018), https://techcrunch.com/2018/10/24/apples-tim-cook-makes-blistering-attack-on-the-data-industrial-complex.

269. EU GUIDANCE ON AI, *supra* note 9, at 33.

270. Russell Brandom, *The NSA's Voice-recognition System Raises Hard Questions for Echo and Google Home*, VERGE (Jan. 22, 2018), https://www.theverge.com/2018/1/22/16920440/amazon-echo-google-home-nsa-voice-surveillance

271. *See, e.g.*, Dake Kang, *Chinese 'Gait Recognition' Tech Ids People by How They Walk*, ASSOC. PRESS (Nov. 6, 2018), https://apnews.com/bf75dd1c26c947b7826d270a16e2658a.

data protection scrutiny of AI, which will be separate from the other regulatory criteria examined herein; and second, a substantive question as to the protective models that should be adopted.

As to the first question, it would be possible to embed an AI-specific data protection model into newly imagined AI regulatory systems. Such a model could encourage domain expertise in examining AI data protection questions. Equally, however, a data protection model operating outside of a general data protection regulatory system could encourage exceptionalism and fragmentation. A better response would be for the AI regulator to require compliance with general data protection rules. This model is consistent with the arguments advanced above for a single AI regulator.[272]

Second, that general data protection regime must include substantive rights and regulatory processes that offer a significant upgrade over the existing regulatory landscape. Specifically, the protection of both individual and societal interests from surveillance and datafication requires a modern, non-domain specific system that uses multiple protective models embodying Fair Information Practice Principles (FIPPs).[273] In the words of a recent Washington Post editorial, "It is time for something new. Legislators must establish expectations of companies that go beyond advising consumers that they will be exploiting their personal information . . . The burden no longer should rest with the user to avoid getting stepped on by a giant. Instead, the giants should have to watch where they're walking."[274] While Congress and technology companies seem to edging towards a federal privacy law they can both live with,[275] privacy advocates are increasingly concerned that any federal legislation will be relatively weak and primarily directed at preempting more robust, emerging state laws.[276]

Detailing such a model for the U.S. is outside the scope of this article. However, data reformers view the EU General Data Protection Regulation (GDPR) as the regulatory exemplar. The GDPR defines "data concerning health" as the "personal data related to the physical or mental health of a natural person, including the provision of healthcare services, which reveal information about his

272. See *supra* Part IV-C.

273. Secretary's Advisory Comm., U.S. Dep't. Health, Educ. & Welfare, DHEW Pub. No. (OS) 73–94, Records, Computers, and the Rights of Citizens (1973), http://www.justice.gov/opcl/docs/rec-com-rights.pdf.

274. Wash. Post Ed. Bd., *Our Privacy Regime Is Broken. Congress Needs to Create New Norms for a Digital Age*, WASH. POST (Jan. 5, 2019), https://www.washingtonpost.com/opinions/our-privacy-regime-is-broken-congress-needs-to-create-new-norms-for-a-digital-age/2019/01/04/c70b228c-0f9d-11e9-8938-5898adc28fa2_story.html.

275. *See, e.g.*, INTERNET ASSOCIATION, IA PRIVACY PRINCIPLES FOR A MODERN NATIONAL REGULATORY FRAMEWORK (2018), https://internetassociation.org/files/ia_privacy-principles-for-a-modern-national-regulatory-framework_full-doc; U.S. Chamber Com., U.S. Chamber Privacy Principles (Sept. 6, 2018), https://www.uschamber.com/issue-brief/us-chamber-privacy-principles.

276. Electronic Frontier Foundation, December 2018 Preemption Letter, https://www.eff.org/document/december-2018-preemption-letter.

or her health status."[277] Its FIPPS-inspired protections include accountability, transparency, purpose and time limitations, and data minimization.[278] Arguably, these requirements are antithetical to the training of AI, its black box algorithms, and the business models of AI and Big Data companies.[279] However, emerging privacy-respecting technologies, including federated learning, differential privacy, and homomorphic encryption, are capable of keeping many of the benefits of AI while protecting the subjects of the underlying data.[280]

Those looking for a U.S. model for improved data protection are paying considerable attention to California's Consumer Privacy Act of 2018.[281] The statute primarily relies on a transparency model requiring data custodians to disclose what information they hold about a data subject and whether it is being sold or otherwise disclosed. The data subject can stop the sale of the information and cannot be discriminated against in service or if they exercise their rights. Unfortunately, the statute has some domain carveouts for HIPAA entities and human subjects research data that preserve exceptionalism[282]

*4. Social Cues, Form, Social Valence, and Empathy*

Historically, effective communication has been promoted as the epicenter of the physician-patient relationship[283] It has also been considered the key to building empathy and trust. Although his context was different, Carlos Pellegrini's words capture the difficulty of "preserv[ing] the interpersonal relationship with our patients in an environment that is driven by business, standardization, and large systems of care that focus on population health rather than individual patients."[284] An extreme but educative example of the downside of advanced healthcare technologies is a recent report that a doctor at a remote location used a telerobot to tell a patient and his family of his impending death.[285]

Communication, empathy and trust are not just about making the healthcare experience a more tolerable, patient-centered one that is attuned to vulnerabilities.

277. Commission Regulation 2016/679, art. 4(15), 2016 O.J. (L 119) 1, 34.

278. *Id.*, art. 5.

279. David Meyer, *AI Has a Big Privacy Problem and Europe's New Data Protection Law Is About to Expose It*, FORTUNE (May 25, 2018), http://fortune.com/2018/05/25/ai-machine-learning-privacy-gdpr.

280. Casimir Wierzynski & Abigail Hing Wen, *Advancing Both A.I. and Privacy Is Not a Zero-Sum Game*, FORTUNE (December 27, 2018), http://fortune.com/2018/12/27/ai-privacy-innovation-machine-learning.

281. Cal. Civ. Code §§ 1798.100 to 1798.198

282. Cal. Civ. Code § 1798.145(c).

283. Jennifer Fong Ha, Dip Surg Anat & Nancy Longnecker, *Doctor-Patient Communication: A Review*, 10 OCHSNER J. 38 (2010).

284. Carlos A. Pellegrini, *Trust: The Keystone of the Patient-Physician Relationship*, 224 J. AM. C. SURGEONS 95 (2017).

285. Dakin Andone & Artemis Moshtaghian, *A Doctor in California Appeared Via Video Link to Tell a Patient He Was Going to Die. The Man's Family is Upset*, CNN (Mar. 11, 2019), https://www.cnn.com/2019/03/10/health/patient-dies-robot-doctor/index.html.

Attentiveness and appreciation of patient circumstances and needs can lead to improved diagnostic insights.[286] To what extent are these ethical and instrumental qualities to be expected of healthcare AI and appropriate to consider as regulatory imperatives?

In the short-term, humans are likely to perform a translational role, with clinicians injecting their own communication skills, empathy, and compassion to smooth over the rough spots in the patient-AI interaction. In some cases, form may serve as a surrogate for compassion. For example, the first generations of caregiver or companion robots have been designed either as humanoid[287] or representative of some other form that engenders a positive social cue, such as cuddly toy[288] or a puppy.[289] Further into the future, questions may arise as to whether the physical form (or future AI holographic representations[290]) of the AI or other social cues will require regulation. Today we know that physical cues such as the gender of a nurse plays into stereotyping, such that male nurses may be viewed as less capable of providing intimate and sensitive care.[291] Some of these questions may become intertwined with decisions about which AI should be vested with humanlike rights and duties. As Cofone argues those decisions likely will be derived from a framework of relative embodiment, emergence, and social valence.[292] The subjectivity inherent in these, particularly social valence, suggests broadly acceptable decisions will evolve quite slowly.

Beyond communication and social cues, empathy and other behavioral, psychological, and psychosocial aspects of healthcare interactions can affect trust, autonomy, and compassion.[293] The question arises, therefore, of whether we will regulate how AI relates to those it cares for. Empathy can be viewed as a touchstone for predicting substitution.[294] For example, it is often suggested that empathetic jobs, including counsellors or medical disciplines such as psychiatry,

286. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 36 (7th ed. 2013).

287. Adam Satariano, Elian Peltier & Dmitry Kostyukov, *Meet Zora, the Robot Caregiver*, N.Y. TIMES (Nov. 23, 2018), https://www.nytimes.com/interactive/2018/11/23/technology/robot-nurse-zora.html ("Zora, which can cost up to $18,000, offered companionship in a place where life can be lonely. Families can visit only so much, and staff members are stretched.").

288. PARO THERAPEUTIC ROBOT, http://www.parorobots.com.

289. Geoffrey A. Fowler, *Aibo the Robot Dog Will Melt Your Heart with Mechanical Precision*, WASH. POST (Sep. 18, 2018), https://www.washingtonpost.com/technology/2018/09/18/aibo-robot-dog-will-melt-your-heart-with-mechanical-precision.

290. *See, e.g.*, *Emergency Medical Holographic Program*, FANDOM (May 24, 2019), http://memory-alpha.wikia.com/wiki/Emergency_Medical_Holographic_program.

291. *See generally* Wen Zhang, Yi-Lan Liu, Demonstration of caring by males in clinical practice: A literature review, International Journal of Nursing Sciences, Volume 3, Issue 3, 2016, 323-327

292. Cofone, *supra* note 92.

293. Other, related values include responsiveness, caring, patient-centeredness, and equity.

294. *See generally* MCKINSEY GLOBAL INST., A FUTURE THAT WORKS: AUTOMATION, EMPLOYMENT, AND PRODUCTIVITY 23 (2017), http://www.mckinsey.com/~/media/McKinsey/Global%20Themes/Digital%20Disruption/Harnessing%20automation%20for%20a%20future%20that%20works/MGI-A-future-that-works_Full-report.ashx.

will be least likely to face substitution.[295] However, an orthogonal question exists as to the extent to which healthcare AI and robots can or should be empathetic with their patients.

Healthcare information technologies have created interpersonal wedges between clinicians and their patients. Examples include the alert fatigue caused by EHR and CDS pop-up warnings[296] and the tendency of physicians to concentrate more on a computer interface than the patient in the same examination room.[297] As suggested above, AI natural language processing and other digital assistants should take over note-taking and allow the physician to concentrate on the patient rather than the technology.[298] However, in some cases AI could take technological intrusion to the other extreme such that the only "persons" in the room will be the patient and a robot. For some, this will prove unacceptable. Michael Mittelman and colleagues argue that "[p]atients need to be cared for by people, especially when we are ill and at our most vulnerable. A machine will never be able to show us true comfort. The ability to understand fully the 'human condition' will always be essential to health management."[299] Empathy may well be too important a property in the diagnostic, treatment, and recovery processes to abandon. To stretch an analogy, "[r]obots that can grill meat, slice tomatoes, stir fry vegetables and even stretch pizza dough are making fast food even faster, but would you trust a chef who has never tasted the food it creates?"[300]

Empathy goes beyond a caring imperative to a protective one. According to Pelligrini, "[i]t is important to consider our patients' vulnerability in the relationship. For physicians to fulfill their commitment to trust, they must protect, rather than exploit, this vulnerability."[301] As we design and regulate healthcare AI, we have to address the extent we believe they should be subject to ethical rules and to an extent be infused with human values.

This is both a technical question--whether our caregiver and other healthcare technologies can be effectively programmed to approximate the empathetic needs/expectation of patients—and a normative one. Do we want our technologies to "fake it"?[302] The analogy once again can be drawn to hybrid and pure electric

295. Kayla Matthews, *Will Robots Replace Therapists?*, WEEK (June 8, 2017), https://theweek.com/articles/694522/robots-replace-therapists.

296. Am. Med. Ass'n Physician Comm. Team, *The Hidden Dangers of HER Pop-up Fatigue*, AM. MED ASS'N (Apr. 20, 2015), https://www.ama-assn.org/practice-management/digital/hidden-dangers-ehr-pop-fatigue.

297. *See generally* Abraham Verghese, *Treat the Patient, Not the CT Scan*, N.Y. TIMES (Feb. 26, 2011), http://www.nytimes.com/2011/02/27/opinion/27verghese.html.

298. *See* Part II.A *supra* (discussing robotic processes).

299. Mittelman, Markham & Taylor, *supra* note 25.

300. David Hambling, *The Chef That Can Make a Gourmet Burger Every 30 Seconds*, BBC (Dec. 6, 2018), http://www.bbc.com/future/story/20181204-the-chef-making-fast-food-even-faster.

301. Pellegrini, *supra* note 284.

302. *See generally* See Geraldine Cremin, *Robots Are Learning to Fake Empathy*, MOTHERBOARD (Apr. 6, 2016), https://motherboard.vice.com/en_us/article/robots-are-learning-to-fake-empathy.

automobiles. The quietness of the driving experience has led some manufacturers to create artificial engine noise that is piped into the cabin.[303] However, automobile noise is more than a matter of taste. From September 2020 hybrid and electric vehicles sold in the U.S. face minimum sound requirements during low-speed operation to alert pedestrians (particularly blind ones) and bicyclists to the presence of such vehicles.[304] A similar rule is being implemented in the EU.[305]

Increasingly, AI personal assistants are being tuned to better understand the context of their interactions with humans. In part, this is achieved by analyzing non-verbal sounds rather than just concentrating on the parsing of language.[306] Current products are beginning to introduce rudimentary examples; Amazon Alexa's has a new "whisper mode" that understands that its instructions are being whispered (perhaps in the presence of a sleeping baby) and so will whisper back.[307] As these technologies evolve, there may be questions about imposing limits on artificial empathy, a question of particular relevance to caregiver bots or even end-of-life comfort bots.[308]

A related issue is whether, as AI gets closer to passing the Turing test,[309] it should announce its own non-obvious artificiality. For example, Google Duplex is a neural network AI that uses natural speech to make completely human-sounding "natural conversations" phone calls to persons (for example, a call requesting a restaurant reservation).[310] When the technology was first demonstrated to the press, questions were raised as to whether the technology was deceptive in not announcing itself as a 'bot.[311] Subsequently, questions were raised about its data-gathering role.[312] These issues will be of particular consequence in the healthcare

303. Sean O'Kane, *Here's the Fake Noise the Jaguar I-Pace Makes When You Hit the Throttle*, VERGE (June 13, 2018), https://www.theverge.com/tldr/2018/6/13/17460934/jaguar-i-pace-electric-car-sound.

304. Federal Motor Vehicle Safety Standard No. 141, Minimum Sound Requirements for Hybrid and Electric Vehicles, 49 C.F.R. § 571 (2019).

305. Jamie Doward, *New Law to Tackle Electric Cars' Silent Menace to Pedestrians*, GUARDIAN (May 6, 2018), https://www.theguardian.com/environment/2018/may/06/new-law-combats-silent-menace-electric-cars.

306. Olivia Tambini, *This Technology Could Make Alexa and Google Assistant Better Listeners*, TECHRADAR, (Nov. 7, 2018), https://www.techradar.com/news/how-sound-recognition-could-make-alexa-a-better-listener.

307. Zeynab Raeesy, *Whisper to Alexa, and She'll Whisper Back*, ALEXA BLOGS (Sept. 26, 2018), https://developer.amazon.com/blogs/alexa/post/c0e7798d-32bc-4549-9c24-97d204a7bf3a/whisper-to-alexa-and-she-ll-whisper-back; *see also* Tom Simonite, *Amazon Wants Alexa to Hear Your Whispers and Frustration*, WIRED (Sept. 20, 2018), https://www.wired.com/story/amazon-alexa-upgrades-whisper-alexa-guard.

308. *End of Life Care Machine*, DAN CHEN, http://www.pixedge.com/lastmoment.

309. Alan M. Turing, *I.—Computing Machinery and Intelligence*, 59 MIND 433 (1950), https://academic.oup.com/mind/article/LIX/236/433/986238.

310. Yaniv Leviathan, *Google Duplex: An AI System for Accomplishing Real-world Tasks Over the Phone*, GOOGLE AI BLOG (May 8, 2018), https://ai.googleblog.com/2018/05/duplex-ai-system-for-natural-conversation.html.

311. Natasha Lomas, *Duplex Shows Google Failing at Ethical and Creative AI Design*, TECHCRUNCH (May 10, 2018), https://techcrunch.com/2018/05/10/duplex-shows-google-failing-at-ethical-and-creative-ai-design.

312. Nate Swanner, *Google Duplex Can Make Calls, But Won't Answer Ethical Questions*, DICE (June 28,

setting as, for example, the algorithms in diagnostic chat bots analyze both speech and speech patterns to recognize depression.[313] The recent EU Guidance on trustworthy AI argues that "]AI systems should not represent themselves as humans to users; humans have the right to be informed that they are interacting with an AI system.."[314]

*5. Eliminating Discrimination, Promoting Health Equity, and Transparency*

Perhaps more than any of the other regulatory imperatives discussed herein the intertwined requirements of eliminating discrimination, promoting health equity, and transparency represent the battle for the "soul" of healthcare AI: whether it can trusted and its commitment to beneficence.

Discrimination by healthcare AI is particularly troubling because the healthcare system itself still struggles with implicit bias.[315] That state was in part a motivating factor for the inclusion of the healthcare nondiscrimination provision in the ACA.[316] Layering healthcare AI on top of the system multiplies such problems because of bias amplification caused by unrepresentative datasets used for training,[317] such as melanoma images primarily captured from persons with light colored skin.[318] As is well-known, AI software has been shown to be capable of gender[319] and race[320] biases, and these biases are likely to perpetuate stereotypes.

AI and big data are particularly adept at population segmentation. This could have important positive effects if, for example, the AI is used to direct services to where they are most needed with the goal of increasing population health[321] or

2018), https://insights.dice.com/2018/06/28/google-duplex-ethical-questions-linger.

313. Luke Dormehl, *New Algorithm Could Help Diagnose Depression by Analyzing the Tone of Your Voice*, DIGITAL TRENDS (July 12, 2016), https://www.digitaltrends.com/cool-tech/machine-learning-depression-detection.

314. EU ] GUIDANCE ON AI, *supra* note 9, at 18.

315. *See generally* DAYNA BOWEN MATTHEW, JUST MEDICINE: A CURE FOR RACIAL INEQUALITY IN AMERICAN HEALTH CARE (2018).

316. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 1557 (2010) (codified at 42 U.S.C. § 18116).

317. Kirsten Lloyd, *Bias Amplification in Artificial Intelligence Systems*, ARXIV 1809.07842 (2018), https://arxiv.org/abs/1809.07842.

318. Adewole S. Adamson & Avery Smith, *Machine Learning and Health Care Disparities in Dermatology*, 154 JAMA DERMATOLOGY 1247 (2018).

319. *See, e.g.*, *Amazon Had to Ditch Ai Recruiting Software that Learned to Penalize Résumés that Included the Word "Women*," CNBC (10 Oct 2018), https://www.cnbc.com/2018/10/10/amazon-scraps-a-secret-ai-recruiting-tool-that-showed-bias-against-women.html.

320. *See, e.g.*, Li Zhou, *Is Your Software Racist?*, POLITICO (Feb. 7, 2018), https://www.politico.com/agenda/story/2018/02/07/algorithmic-bias-software-recommendations-000631.; Sarah Perez, *Microsoft Silences Its New A.I. Bot Tay, After Twitter Users Teach It Racism [Updated]*, TECHCRUNCH (Mar. 24, 2016), https://techcrunch.com/2016/03/24/microsoft-silences-its-new-a-i-bot-tay-after-twitter-users-teach-it-racism/.

321. *See, e.g.*, Joanne Lynn, Barry M. Straube, Karen M. Bell, Stephen F. Jencks & Robert T. Kambic, *Using Population Segmentation to Provide Better Health Care for All: The "Bridges to Health" Model*, 85 MILBANK Q. 185; *Id.* at 209-12 (discussion).

delivering precise or personalized healthcare.[322] However, such segmentation could be used for "technological redlining,"[323] impacting access to care (for example, by denying healthcare insurance to the sick or imposing higher premiums or tiering drugs on the basis of diseases associated with sexual preference, age, or ethnicity).[324] In such latter scenarios, AI would transgress the principle of healthcare solidarity that is the foundation of inclusive healthcare systems.[325]

Like other health information technologies, healthcare AI is projected to improve access, reduce cost, and improve quality. The health equality (non-discrimination) question is whether those improvements will accrue to all or only a section of the population. The health equity question is broader, asking whether we can reduce not just health disparities but also their determinants.[326] According to Andy Slavitt, a CMS administrator under president Obama who is now leading a venture capital firm, "We need to stop investing in the third Fitbit for the 50-year-old upper-class person and start innovating for people who have common diseases and conditions, but live in communities with low access to care."[327]

In addition to decisions made by public and private payors in setting their reimbursement policies, the health equity question may play out in product and service marketing. For example, will healthcare AI be positioned as a premium service like today's healthcare concierge models?[328] Or will things resolve in the opposite direction, with AI established as a low-cost alternative healthcare system for the many, while the few will receive their healthcare from "real" doctors? Whatever the direction, a fundamental inquiry must be whether healthcare AI will increase or decrease healthcare disparities. An obvious example is the caregiver robot. With our declining birthrate, a still robust life expectancy notwithstanding the rampant "diseases of despair,"[329] and nativist-inspired controls on immigration,

322. *See, e.g.*, Press Release, GE Healthcare, AI-Powered Precision Medicine: Forging a Path to Personalized Health, http://www.healthforum.com/field-insights/content/ge-2018-1011-ar-ai-powered-precision-medicine.shtml.

323. *See generally* Jeffrey Vagle, *Technological Redlining*, CTR. INTERNET & SOC'Y (July 19, 2016), http://cyberlaw.stanford.edu/blog/2016/07/technological-redlining

324. *See generally* Sharona Hoffman, *Big Data's New Discrimination Threats*, *in* BIG DATA, HEALTH LAW, AND BIOETHICS 85 (Glenn Cohen, Holly Fernandez Lynch, Effy Vayena & Urs Gasser, eds., 2018).

325. *See generally* James E. Sabin, *Individualism, Solidarity, and U.S. Health Care*, 14 VIRTUAL MENTOR 415 (2012).

326. PAULA BRAVEMAN, ELAINE ARKIN, TRACY ORLEANS, DWAYNE PROCTOR & ALONZO PLOUGH, WHAT IS HEALTH EQUITY? AND WHAT DIFFERENCE DOES A DEFINITION MAKE? (2017), https://www.rwjf.org/content/dam/farm/reports/issue_briefs/2017/rwjf437393.

327. Christina Farr, *The Guy Who Battled Republicans Over Obamacare is Investing in Health Tech for the 99 Percent*, CNBC (Mar. 4, 2018), https://www.cnbc.com/2018/03/04/andy-slavitt-ex-medicare-medicaid-chief-becoming-health-investor.html.

328. *See generally* Russ Alan Prince, *What Is Concierge Healthcare?*, FORBES (May 30, 2013), https://www.forbes.com/sites/russalanprince/2013/05/30/what-is-concierge-healthcare.

329. *See generally* Anne Case & Angus Deaton, *Mortality and Morbidity in the 21st Century*, 2017 BROOKINGS PAPERS ON ECON. ACTIVITY 397, 398 (2017) (drug overdoses, suicides, and alcohol-related liver mortality).

who will take care of our aging population? In other words, will we have affordable caregiver robots at scale? If we continue to struggle politically and economically, the question of universal healthcare becomes whether AI can positively intervene, following the example of Google's Cityblock subsidiary that creates community-based clinics ("Neighborhood Hubs") in underserved urban areas.[330] Or, as Nicholson Price argues, are ideas of AI-powered, democratized medical expertise doomed because of the "disconnect between high-resource training environments and low-resource deployment environments will likely result in predictable decreases in the quality of algorithmic recommendations for care, limiting the promise of medical AI to actually democratize excellence."[331]

Transparency has a least two meanings in the context of healthcare AI. The first is transparency in governance, and this meaning intersects with some of the data protection and regulator discussions above. The second meaning is a question of technological transparency: if we do not understand how healthcare AI makes decisions, how can we assess whether a clinician should rely on the technologies (or rely on his or her professional training and ignore the technologies)? AI opaqueness also dramatically amplifies the difficulty of identifying and curing implicit bias.

Jay Katz ended his *Silent World* exposé with the argument that "both [physician and patient] must be trusted, but that they can only be trusted if they first learn to trust each other."[332] Katz "only" had to confront informational asymmetry and a deficiency in physician communication built on paternalism. Healthcare AI poses questions of a completely different order of difficulty, the most obvious being that if, through the beneficence of its programmers, the AI decided to break its silence, it is wholly unclear whether it could or would say anything remotely comprehensible to its patient or even a nearby physician.

The preferred solution, and so a regulatory imperative, is algorithmic accountability.[333] According to the recent EU Guidance on AI ethics, "a fully transparent procedure should be made available to citizens, including information on the process, purpose and methodology of the scoring… Ideally the possibility of opting out of the scoring mechanism when possible without detriment should be provided – otherwise mechanisms for challenging and rectifying the scores must be given.."[334]

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330. *Our Story*, CITYBLOCK, https://www.cityblock.com/about.

331. W. Nicholson Price II, *Medical AI and Contextual Bias*, 18 YALE J. HEALTH POL'Y L & ETHICS __ (2019), 21 YALE J.L. & TECH. __ (2019).

332. JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 229 (1984).

333. *See generally* DATA & SOCIETY, ALGORITHMIC ACCOUNTABILITY: A PRIMER 10-11 (2018), https://datasociety.net/wp-content/uploads/2018/04/Data_Society_Algorithmic_Accountability_Primer_FINAL-4.pdf.

334. EU GUIDANCE ON AI, *supra* note 9, at 34.

Consider, for example, "Deep Patient," an AI project at Mount Sinai Hospital where the AI was given access to 700,000 patient records and then tasked with assessing the charts of new patients. It turned out that the system was "incredibly good at predicting disease."[335] But what if it had been a failure? Would stakeholders including providers and patients have been able to question it to learn about its errors? Equally, how can a patient make an informed decision about proffered healthcare without understanding, even in very general terms, how the decision about his or her health is being made? The "transparency" answer to these questions is that we should be able to interrogate decision-making algorithms. Subsumed in that question is a more practical dichotomy: to trust the technology or abandon it.[336]

A related transparency issue, more akin to conflicts of interest, concerns the bilateral data relationships that arise between analytics/AI service providers and data custodians. A primary example would be the relationship between Google's DeepMind and the NHS Royal Free in the UK.[337] Another is when an AI-based employee recruitment company also supplies human resource software that uploads employee data to the recruitment company.[338] Technologically, this is how it *should* work, using a feedback loop to continually improve the data and sharpen the algorithm. However, while those feedback loops may benefit both the employer and the recruitment company or the UK trust and Google, they may not be such a clear win for the data subjects.

## V. CONCLUSION

Examination of the normative expectations for and regulatory models applicable to healthcare AI are in their infancy. Some readers may take comfort from the traditionally lagged adoption of technology exhibited by healthcare—maybe other industries will have to address the issues sooner, with policymakers coming up with properly calibrated regulation. However, superior results may be delivered if healthcare stakeholders are at that regulatory table and contribute to the dialog.

These issues are fundamental to the future of healthcare and population health and will inform the next several generations of questions about healthcare access, quality, and cost containment. At the very least, any regulatory model must be

335. Will Knight, *The Dark Secret at the Heart of AI*, MIT TECH. REV. (Apr. 11, 2017), https://www.technologyreview.com/s/604087/the-dark-secret-at-the-heart-of-ai.

336. *Id.*

337. *See generally* Natasha Lomas, *UK Watchdog Has Eyes on Google-DeepMind's Health App Hand-off*, TECHCRUNCH (Nov. 14, 2018), https://techcrunch.com/2018/11/14/uk-watchdog-has-eyes-on-google-deepminds-health-app-hand-off.

338. Noam Scheiber, *A.I. as Talent Scout: Unorthodox Hires, and Maybe Lower Pay*, N.Y. TIMES (Dec. 6, 2018), https://www.nytimes.com/2018/12/06/business/economy/artificial-intelligence-hiring.html.

expansive and multi-faceted and not dependent on narrow technocratic evaluation of device safety or physician licensure.